

**ANDERSON EXHIBIT 10A**

# MEDICARE DRUG REIMBURSEMENTS: A BROKEN SYSTEM FOR PATIENTS AND TAXPAYERS

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## JOINT HEARING BEFORE THE SUBCOMMITTEE ON HEALTH AND THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED SEVENTH CONGRESS FIRST SESSION

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## **MEDICARE DRUG REIMBURSEMENTS: A BROKEN SYSTEM FOR PATIENTS AND TAXPAYERS**

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**FRIDAY, SEPTEMBER 21, 2001**

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON ENERGY AND COMMERCE,  
SUBCOMMITTEES ON HEALTH,  
AND OVERSIGHT AND INVESTIGATIONS,  
*Washington, DC.*

The subcommittees met, pursuant to notice, at 9:40 a.m., in room 2123, Rayburn House Office Building, Hon. Michael Bilirakis and Hon. James C. Greenwood presiding.

Members present Subcommittee on Health: Representatives Bilirakis, Barton, Upton, Greenwood, Burr, Ganske, Norwood, Bryant, Buyer, Pitts, Tauzin (ex officio), Brown, Barrett, Capps, Hall, Pallone, Deutsch, Stupak, Engel, and Green.

Members present Subcommittee on Oversight and Investigations: Greenwood, Bilirakis, Stearns, Gillmor, Largent, Burr, Bass, Tauzin (ex officio), Deutsch, and Stupak.

Staff present: Chuck Clapton, majority counsel; Yong Choe, legislative clerk; and Edith Holleman, minority counsel.

Mr. GREENWOOD. Good morning. This joint hearing of the Energy and Commerce Committee's Subcommittees on Oversight and Investigation and Health will now come to order. Before we proceed with the members' opening statements, Mr. Bilirakis and I would like to make a few remarks.

Among the thousands of lives so hideously taken from us on September 11 was that of Lisa Raines. Lisa Raines was the senior vice president of government relations for Genzyme Corporation. Those of you who knew her know she was a giant in the biotech and pharmaceutical industry for at least the past 15 years and a friend to many. Her memorial service is scheduled for 11 o'clock this morning, and for that reason these subcommittees considered very seriously postponing once again this hearing. We wish we could have done that.

By the conclusion of this hearing, I think it will be apparent to all the urgency to fix this broken AWP system. Given the fact that we have only about 4 weeks for session for this year, we concluded that it was impossible, particularly given next week's short schedule, to postpone this hearing once again. We regret we had to make that decision because we know there were many who would like to be here, but also felt their priority was to be at the memorial service.

Having said that, I would like to recognize Chairman Bilirakis for his comments.

Mr. BILIRAKIS. Thank you, Mr. Chairman.

On September 11 of this year, American's calm was shattered by a horrendous act of terrorism that will long be remembered. Our thoughts and prayers are with those whose lives have been forever altered by this tragedy.

When American Airlines flight 77 went down, the health community lost a dear friend and respected colleague, Lisa Raines. Lisa was a senior vice president of government relations for Genzyme Corporation. Lisa had worked closely and often with the Energy and Commerce Committee through the years, working to enact the Drug Export Amendments Act of 1986, the prescription drug user fee, PDUFA, the FDA Export Reform and Enhancements Act of 1996, and the Food and Drug Administration Monitorization Act, or FDAMA.

A vital member of the Washington biotechnology and pharmaceutical community, Lisa previously worked for the Industrial Biotechnology Association, now BIO, and the Congressional Office of Technology Assessment. Lisa's expertise and insight as well as her bright personality and charm will be missed by this committee, the Congress and the health community. I think the publication BioCentury said it best when it said Lisa was as much a fixture of the biotech industry as a double helix, and it is hard to comprehend that she is gone. She leaves a hole in the industry's relationship with the outside world that will be difficult to fill.

I join with the chairman and members of this committee as we offer our condolences and prayers to Lisa's family and friends. Please join us in a moment of silence in honor of Lisa Raines.

[The prepared statement of Hon. Michael Bilirakis follows:]

PREPARED STATEMENT OF HON. MICHAEL BILIRAKIS, CHAIRMAN, SUBCOMMITTEE ON HEALTH

I'd like to thank Chairman Greenwood for joining me today to examine the issues surrounding the current system for Medicare drug reimbursement. The Health Subcommittee has spent a considerable amount of time in this Congress examining how best to add a comprehensive prescription drug benefit to the Medicare program. This hearing builds off of work we began in the last Congress where we examined the reimbursements for the limited drug coverage currently available in the Medicare program.

I'd like to welcome and thank all of the witnesses, including Tom Scully from CMS and Bill Scanlon from GAO. We rely often on these government officials and their offices for factual information and detailed analysis, thank you for coming today. I'd also like to welcome Mr. Zachary Bentley from my home state of Florida. I know that your testimony, and that of all the witnesses, will help inform the Committee and the public about the issues regarding Medicare's current reimbursements to health care providers for certain drugs used to treat patients.

The Medicare program currently provides coverage for a small number of drugs, limited principally to those that are administered incident to a physician's treatment or in conjunction with covered durable medical equipment, such as inhalation drugs used with a nebulizer. Since at least 1992, Medicare has determined the appropriate reimbursement price for these covered drugs by referring to an industry trade publication known as the Red Book, which lists what manufacturers purport to be the Average Wholesale Price for their drugs. Since 1997, providers who administer these drugs to Medicare beneficiaries have been reimbursed for their cost at prices equal to Average Wholesale Price (AWP) minus five percent. Of this set amount, Medicare Part B covers 80 percent, while Medicare beneficiaries can be required to pay the remaining 20 percent as a co-payment. Today's hearing will examine how Medicare's current reimbursement system, for the relatively few drugs that

are covered, is costing beneficiaries and taxpayers more than is necessary and may be having an adverse impact on the health of some of our most vulnerable citizens.

I recently toured a Clearwater oncology center in my Florida district and I can tell you what great work oncologists do and how important their work is to so many Americans. At the request of my constituent Dr. Marcos Joppert I would like to admit this white paper on oncology payments into the record.

This will prove to be a lengthy hearing and thus I will limit my opening statement so that we may get to the important testimony of the witnesses—who I again thank for their effort and cooperation.

Mr. GREENWOOD. Thank you, Chairman Bilirakis, for your comments. As the President said, let us get back to work.

Let me begin by thanking all of the witnesses who have agreed to testify today at today's hearing. Your testimony will shed light on an insidious problem about how the Medicare program reimburses health care providers for certain drugs used to treat very sick patients. Today's hearing, which is a culmination of years of investigative and audit work performed by subcommittee staff and the witnesses from our first panel, will examine how Medicare's reimbursement system for the relatively few drugs currently covered by the program is costing Medicare and its beneficiaries roughly \$1 billion every year in overcharges while having an adverse impact on the health care of some of our most vulnerable elderly and disabled citizens.

We will hear how the manufacturer of a chemotherapy drug like Vincasar sold it to health care providers for \$7.50, then reported the price to Medicare as \$740. Medicare paid the doctor almost \$600 for the same drug, and the poor sick patient got hit up for another \$150.

We will also hear today from the Department of Health and Human Services Office of Inspector General about how many other overcharges result in Medicare paying more than \$886 million every year in inflated prices for just a sample of 24 Medicare-covered drugs reviewed by that office. The total figure for all Medicare-covered drugs very likely exceeds a billion dollars each year.

It should be noted that Medicare currently reimburses for a very limited number of drugs, chemotherapy agents, blood-clotting factors used to treat hemophilia and inhalant drugs used to treat respiratory diseases, the total cost of which is approximately \$4 billion a year. A billion dollars of taxpayer dollars is wasted every year in this program because under current Federal law and regulations, Medicare is paying for drugs at AWP. AWP, or average wholesale price, could also be an acronym for "ain't what's paid." It is quite clear that despite its name, AWP is not the average wholesale price at which these drugs are sold to health care providers or anything close to it. To the contrary, it appears that for many of these drugs, AWP is simply an artificial price established by certain drug manufacturers and reported to industry trade publications for purposes of third-party reimbursement, a price which bears little, if any, relationship to what is actually paid for these drugs by health care providers.

Before we go further, however, let us be clear about one thing. Most drug companies establish AWP's that are, in fact, fairly reliable indicators of average wholesale prices, but in those instances where they do not, the difference between what providers actually pay and what Medicare reimburses results in what is commonly re-

ferred to as a spread, an unwarranted profit pocketed by the health care provider each time he or she utilizes that particular drug. We will see evidence today demonstrating how some drug manufacturers have manipulated the reported AWP and thus the spreads on their drugs in order to create financial incentives for providers to use their drugs over competitors' products. In doing so they have provided a financial windfall to the health care providers that enables them to sell more of their drugs. In the words of one manufacturer, this is a win-win-win situation for manufacturers, wholesalers and health care providers. The big losers in these marketing ploys are the Medicare program, its elderly and disabled beneficiaries, and the American taxpayer, all of whom have to foot the bill for greatly inflated drug costs.

Of even greater concern to America's seniors than the impact of having to pay inflated copayments on drugs based on prices that are sometimes tens or hundreds of times higher than what their health care provider actually paid for the drugs is that they also may have had the quality of their health care adversely affected by this perverse system. We will hear how the profits available for utilizing certain drugs appear to be improperly affecting some health care providers' clinical decisions, influencing them to provide unnecessary care and utilize drugs based on profit margins rather than therapeutic efficiency.

For example, we will learn of cases in which the utilization of certain drugs skyrocketed without any reasonable clinical justification after manufacturers created large Medicare-funded financial windfalls to health care providers to encourage them to use their drugs. In one such case, and the case is on the screen there, Medicare utilization and reimbursements of the inhalation drug ipratropium bromide used to treat respiratory diseases increased more than twentyfold between 1995 and 2000, from \$14 million in 1995 to more than \$300 million in 2001, a time period in which the drug went from having no spread to having a Medicare-covered spread of 300 percent.

We will also hear about how terminal cancer patients received aggressive courses of chemotherapy, raising questions about whether the motivation for providing such care was the profit available from the use of Medicare-covered chemotherapy drugs.

Congress has long championed the fight against cancer. We supported increased funding for research at the National Institutes of Health and to improve the quality of clinical care. We fought to ensure that the proper incentives exist to develop new and innovative drugs. To then learn of the instances in which quality of patient care might have been adversely affected by the financial benefits available to providers from utilizing certain drugs is nothing short of outrageous. While providers and their associations strongly denied being influenced by any such considerations, we cannot tolerate a system that could leave such motivations even open to question.

Providers do not generally deny that they often reap huge profits on the utilization of certain Medicare-covered drugs. Instead they argue that they currently depend on these profits in order to make up for other services in which Medicare under-reimburses them. We will hear testimony today that will confirm that like many

other groups of providers, these providers who administer Medicare-covered drugs are not fully reimbursed for all the costs associated with treating their patients.

We should reimburse all providers fairly for their expenses; nevertheless a system in which the use of certain drugs can influence clinical medical decisions is not the answer. Life-and-death decisions about the treatment of those who suffer from the scourge of cancer should be governed exclusively by a concern for the patient and not the margin of profit.

When this hearing is over, my colleagues and I will work with this new administration as well as providers and drug companies to scrap this flawed system. We will need to develop a solution that results in Medicare paying prices for drugs that are closer to the actual prices paid by health care providers. Similarly we will need to take steps to ensure that health care providers are sufficiently reimbursed for all of their services so that the quality of care they provide to the Medicare patients is not diminished by changes made to the drug reimbursement system.

I look forward to hearing from CMS Administrator Scully today about what steps his agency can be directed to take to guarantee that this scandal is resolved as quickly as and effectively as possible. In these new and perilous times when our Nation and our people may be called upon to make great personal and financial sacrifices in the defense of our country, Congress has the heavy burden of making sure that every available resource is used wisely, and if we hope to find a way to pay for an expanded Medicare drug benefit that will assist seniors to purchase prescription drugs even as we take on a renewed and determined defense of our homeland, these abuses cannot be tolerated.

If we are going to provide Medicare beneficiaries with a comprehensive prescription drug benefit, and we must, we have to stop wasting billions of dollars on the existing program. We will need every Medicare dollar we can find. In addition, our efforts to resolve this problem will hopefully serve as an example for those State Medicaid problems and other third-party payers who face similar issues in their reimbursements for the costs of drugs. This in turn could result in billions of additional dollars in taxpayers' savings beyond those amounts that were discussed above applicable only to Medicare.

There is one more important lesson in all of this. Government-run programs such as this, which escape the rigors and discipline of the marketplace, inevitably end as expensive failures. It is only by forming an honest partnership between Government and private sector that we can hope to build a new and better Medicare program on a sound financial footing.

Again, I wish to extend my thanks to all of the witnesses who agreed to appear at today's hearing to inform us about this serious problem. While I am disappointed that the invited drug manufacturers declined to testify today about these practices and how the system could be reformed, I am nonetheless committed to moving forward on this issue in a positive and productive manner with all parties so that we can fix this system quickly and protect America's Medicare beneficiaries from further financial and personal harm.

The Chair yields 5 minutes to the ranking member of the Oversight and Investigations Subcommittee, Mr. Deutsch.

Mr. DEUTSCH. Thank you, Mr. Chairman. Thank you also for your opening comments. I think for any of us not to mention September 11 would be a mistake. This is, I know, my first hearing since then, and I think for all of us on this dais, and America and the world changed on September 11, and even our work here in a sense has changed. I think if we do everything we do in our lives, I think all Americans do everything they do a little bit differently, in fact maybe a lot differently than—after September 11.

Let me mention three things and summarize an opening statement. The three things in terms of the issue in front of us that are most disconcerting, the first issue is there appears to be some evidence, and I hope it is developed in the course of the hearing, that some manufacturers, by increasing the spread on the average wholesale price, have encouraged physicians to actually do substitutions on medication. That is obviously incredibly disserving from best medical practices to best financial incentives for that individual position or office, and that is obviously a system which is fundamentally broken.

The second issue, which again is a very disconcerting issue, is that for Medicare beneficiaries, as most people are aware, their copayments are based upon Medicare reimbursements, not on the reimbursement that the physician is paying for the drug. So there apparently, again, the testimony, I think, will be brought out during the course of this hearing cases, and apparently many cases, where the 20 percent copayment is, in fact, more than the physician actually paid for the drug, and obviously the situation of Medicare beneficiaries, that is an absolutely absurd situation.

As we develop this—and this is part of the problem, and I am looking forward to testimony about this as well—is we have a situation where we have a reimbursement system which I don't think anyone can honestly defend in terms of the average wholesale price, but I think we also have a reimbursement system on the physicians' side that is hard to defend as well. Obviously these two things are related. I guess there is debate about how related they actually are, but I think that we need to acknowledge that, and we need to do our part in terms of fixing it.

I have a lengthy statement, which I think at this point, based on the time, I would rather submit for the record. So I will submit that for the record as well as Mr. Dingell has a statement and the chairman of the Ways and Means Committee, Mr. Stark, also has a statement that they were going to submit for the record as well.

[The prepared statement of Hon. Peter Deutsch follows:]

PREPARED STATEMENT OF HON. PETER DEUTSCH, A REPRESENTATIVE IN CONGRESS  
FROM THE STATE OF FLORIDA

Thank you, Mr. Chairman, for holding this very important and long overdue hearing. For many years, the Inspector General of the Department of Health and Human Services—like a voice crying in the wilderness—has been issuing reports telling the Department and the Congress that the taxpayers were being gouged for drug payments under both the Medicaid and the Medicare programs. These federal programs were paying providers the published Average Wholesale Price or AWP for prescription drugs which was, in truth, far more than the drug manufacturers were charging them. The program now has spun so far out of control that the annual overpayments may be as high as \$1.9 billion. We will hear testimony today of a

scheme where doctors prescribing drugs to be administered in patients' homes wanted a kickback from the infusion companies based on the AWP spread over actual cost. The Justice Department and numerous states have been investigating this situation, and hundreds of millions of dollars have been recovered.

Only Congress and the reimbursing agency have been silent. In fact, we—particularly those on the other side of the aisle who are concerned about anything that they think might resemble setting prices—have stopped almost every reform effort. We must take steps now to eliminate this abuse.

Over the years, Medicaid at both the federal and state levels has been able to get a 15 percent discount from the AWP plus a rebate from the manufacturer that can reach up to another 15 percent based on the reported Average Manufacturers Price or AMP. But drug manufacturers, the Medicare carriers, the Centers for Medicare and Medicaid Services (CMS) and its predecessor, the Health Care Financing Administration, or HCFA, the Congress and the providers have all combined to establish, further and abuse the fraudulent Medicare drug reimbursement system. The drug companies—who, Mr. Chairman, are notable by their absence at this hearing since they *were*, I believe, the instigators of this scheme—reported artificial and false Average Wholesale Prices to the public for reimbursement purposes while at the same time *not one* of their customers was paying those prices.

The Medicare carriers paid those prices and failed their responsibility to assure that actual drug prices were being paid. HCFA tried to reform the system, but often gave up because of provider objections. Congress and the Executive branch also aborted HCFA's reform attempts by citing the Paperwork Reduction Act and requiring reports from the General Accounting Office before any changes could be made. The reports we are receiving today are the most recent mandated by Congress in place of real action.

As we will hear in testimony today and is verified by the documents to be placed into the record, the pricing abuses have reached the point at which drug manufacturers use the "spread" between the AWP and the actual price paid as a marketing tool to sell their products. Not only does the taxpayer get gouged; so does the Medicare beneficiary who is required to pay 20 percent of the total cost of the drug. A chart prepared by one of the witnesses provides *nine* examples in which the 20 percent copayment covered the entire cost of the drug to the provider. A breast cancer treatment costs the provider \$450; it charges Medicare \$1,359. The co-pay is \$272; the profit is \$909.

Some of the providers of out-patient drug treatment that we will hear from today will say that they are using these excessive payments to cover their treatment costs in other areas. They allege that they will not be able to continue providing service if this is not remedied. If that is true, their arguments and those of other specialties suffering from similar under payments should be documented and presented to CMS. However, there is a pilot Medicare drug program in Texas underway in which competitive drug pricing is used. The costs are down, and there is no evidence of the withdrawal of any providers. We must also remember that the General Accounting Office has found a number of times that there is little or no evidence of under-reimbursement of providers under either Medicare or Medicaid.

Mr. Chairman, I look forward to hearing from these witnesses.

Mr. GREENWOOD. Without objection, all members' opening statements will be submitted for the record.

The Chair recognizes the chairman of the full committee, the gentleman from Louisiana, Mr. Tauzin.

Chairman TAUZIN. Thank you, Mr. Chairman.

Mr. Chairman, I, too, want to thank you for the moment of silence for the recognition of Lisa Raines and the loss of so many friends across America, but also your determination to move forward with this important hearing, and I want to congratulate the staff who worked with you to develop this hearing, which I believe will highlight one of the most important abuses within the Medicare system that this committee has ever uncovered.

What you will see today is a situation that has turned Adam Smith on his head; a situation which, because of the system in which we reimburse physicians for the cost of certain drugs particularly in chemotherapy and inhalants and several other categories, but the Government of the United States is paying in some

cases many times the price that the physician is actually buying the drugs for. Worse than that, worse than this loss of billions of dollars of Medicare dollars that taxpayers put up to make sure that our mothers and fathers and grandmothers and grandfathers and all our relatives are properly cared for in the Medicare health system and in the Medicaid system, by the way, worse than this loss of the funds that are critical to sustain the program is the fact that the patients, those loved ones we protect under this system, are being required under this system to put up not 20 percent of the cost of the drugs to the doctor, but in one case—and I have a chart I want to show you up there, the Medicare 20 percent copay chart—in one case with a drug called Doxorubicin, the patient is putting up not 20 percent, but 200 percent of the cost. The patient who is supposed to put up 20 percent is putting up 200 percent of the true cost of the drug.

Look at the drug etoposide. In that case the patient is putting up not 20 percent, but 300 percent of the cost, triple the cost the doctor spends on the drug. The poor Medicare patient ends up tripling his contribution for the total cost of that drug instead of putting up just one-fifth of the cost.

Look at the drug Leucovorin. It sounds like a character in *The Godfather*, maybe properly named. In that case the Medicare patient is putting up 500 percent of the cost of the Medicare drug as a copay.

Look at the column of the Florida Medicare allowable. Look at what the doctor is getting back from the Medicare system in Florida for those three drugs. The doctor is paying for Leucovorin \$1.25 for 50 milligrams, and the patient is putting up \$7.09, and the Medicare system is paying the doctor up to \$35.47. That is the spread we have been talking about. The spread between the real cost of the physician and the cost the Medicare system is paying for the drug, and perhaps the copay cost the poor patient has to put up, in some cases as high as 500 percent of the real cost of the drug to the doctor. How can we tolerate such a system any longer?

Mr. Chairman, I really appreciate your uncovering this and allowing this hearing literally to go forward when I know most people are concerned about us getting back to work too fast. We have got to get to work on this one fast. Not only does this rob the Treasury and the Medicare fund of billions of dollars that should not be paid because they are not the average wholesale prices, they are some kind of awful artificial wholesale price, but, again, it turns Adam Smith on his head.

Think about this with me for a second. We introduced generic drugs into the system to create competition. Do you know what happens to the system when a generic drug comes into play? Evidence we have that we will develop today indicates that when a generic drug comes into competition with a patent drug finally, the price doesn't come down. The price goes up because both of the drug companies understand that if they are going to sell that drug to the doctor, they have got to give them a bigger spread. So they are in competition to give them a bigger spread, and they both post higher and higher artificial wholesale prices to the Medicare system.

It is a game that turns ordinary economics on its head. As competition comes into the field, prices go up not only to the government, but to the poor patient who has to pay not 20 percent, but 300, 400, 500 percent of the cost of the drug. It is a rotten system.

And, Mr. Chairman, perhaps the most pernicious part of it all is the evidence you uncovered with our staff that indicates that—at least some evidence that in some cases chemotherapy may be dumped into patients in the last 3 years of life because there is so much profit to be made. There is so much profit to be made on some of these drugs, when that chemotherapy just literally rips up bodies and the welfare of those patients in the last 3 months of their life, maybe chemotherapy that might not be needed. Maybe drugs are being substituted when a better drug is available because the drug substituted has a better kickback, if you will.

Now it is time the system be reformed, Mr. Chairman. I want to thank you and the staff for uncovering it as much as you have. If there was one thing certain about this, it is that the responsibility lies in this Congress to straighten it out. We permitted this to happen. We have got to straighten it out. And I have asked you to do one thing before you went forward with this hearing, and that was to be prepared to straighten it out; not just to talk about it, not just to make Americans understand how rotten the system is and how all the players in it hate it as much as I hope we all do now, because we are all forced to play this ugly game with one another, but more importantly you are prepared to cure it. You and Mr. Bilirakis, the chairman of our Health Subcommittee, are prepared to offer solutions not next year, but immediately, and I think every patient in America who is getting skinned by this system to the tune of 500 percent of the real cost of the drug when they ought to be paying one-fifth of it, I think they will thank you today for doing the Nation a real favor by getting rid of a system that robs the American taxpayer, the Medicare system, corrupts the system, deprives patients of their critical dollars at a time most needed, and in some cases may encourage the few, I hope, unscrupulous people to improperly medicate people in their worst hours, in their last final hours on this Earth.

I yield back the balance of my time.

[The prepared statement of Hon. W.J. “Billy” Tauzin follows:]

PREPARED STATEMENT OF HON. W.J. “BILLY” TAUZIN, CHAIRMAN, COMMITTEE ON  
ENERGY AND COMMERCE

Let me begin by thanking Subcommittee Chairmen Greenwood and Bilirakis for holding this joint hearing today. I appreciate their efforts to highlight the problems that this Committee has uncovered concerning Medicare drug prices. I sincerely hope that, by holding this hearing, we can begin the process of fixing these problems.

As Chairman Greenwood has pointed out, the Committee has uncovered disturbing evidence that Medicare may be wasting over one billion dollars a year, paying unnecessarily inflated prices for drugs. This intolerable situation not only affects the finances of the Medicare program and the American taxpayer, but also directly impacts the finances of America’s Medicare beneficiaries.

We all have parents, grandparents, friends, or neighbors who depend on Medicare to help them pay for the small number of drugs that Medicare currently covers. It is unacceptable that—because of the government’s ineptitude in the way it pays for these drugs—our loved ones are being forced to pay inflated co-payments for their chemotherapy drugs to cure their cancers, inhalation drugs to treat their respiratory diseases, and antibiotics to treat their infections.

The Inspector General's Office at the Department of Health and Human Services recently prepared a report for me that shows how, last year alone, Medicare beneficiaries paid an extra *one hundred and seventy seven million* dollars in co-payments due to inflated reimbursements for Medicare-covered drugs. For example, this means that cancer patients are paying an extra \$6.56 for each dose of Doxorubicin, and an extra \$3.01 for each dose of Leucovorin Calcium. These costs quickly add up in treatment regimens requiring multiple doses, and often can make an enormous difference for somebody living on a fixed-income.

Of even greater concern to me is the evidence uncovered by the Committee indicating that these overpayments to health care providers may be affecting the quality of care received by Medicare patients. Patients may not be receiving the most clinically effective treatments, due at least in part to the perverse incentives of the Medicare reimbursement system. The Committee has learned of instances in which the Medicare reimbursement "spreads" on certain older, less clinically effective drugs were so large that drug manufacturers were unable to successfully market improved, more clinically effective drugs to health care providers.

The Committee also has learned that some patients may be receiving unnecessary medical therapies—again due at least in part to the excessive reimbursements available to health care providers for use of certain drugs. Given the powerful effects that these drugs can have on patients, we must ensure that no patient receives a particular drug regimen for any reason other than to provide the best clinical care.

Medicare's broken reimbursement system also turns Adam Smith's conception of market competition on its head. Only under Medicare could a drug manufacturer *raise* its prices, or at least the ones it reports for purposes of government reimbursement, to increase sales. The Committee has uncovered evidence that at least one manufacturer has done exactly this. Upon learning that a competitor raised its reported Average Wholesale Price and thus its Medicare reimbursement spread, this manufacturer responded promptly in the same fashion, noting how simple it was to change its AWP—something that could be done overnight—in order to maintain sales.

Here's another example of this crazy AWP system at work: an internal drug manufacturer document from 1994 discusses the consequences of increasing the spread on one of its top drugs, quote, "in order to increase the amount of Medicaid reimbursement for clinical oncology practices." In a particularly blunt assessment, the author notes with irony how, quote, "on the surface, it seems that in response to the entrance of a competitor in the market, Glaxo has actually raised its price on Zofran—perhaps twice in one year." The memo goes on to ask: "How do we explain a single 9% increase in the AWP? What arguments can we make to explain to congressional watchdogs that we are cost-shifting at the expense of government?" Despite recognizing the troubling issues raised by such a pricing strategy, Glaxo succumbed to the system anyway, raising its Zofran AWP two months later, while actually lowering the real costs of the drug to providers.

Medicare also distorts the benefits of the generic drug market. Generic drugs hold the potential to decrease pharmaceutical costs dramatically, through price competition with brand-name drugs. Under Medicare, however, the Committee has uncovered situations in which some generic manufacturers competed for market share by *raising* the prices they reported to the government—thus increasing costs to taxpayers and patients—while actually selling the drugs to providers at steep discounts.

Today's hearing will highlight these abuses. It is my hope that, by bringing this information to the attention of Congress and the American public, we can build support for reforming the currently flawed Medicare drug reimbursement system. Chairmen Greenwood and Bilirakis should be commended for their role in this effort, and I look forward to working with them and all the Members of this Committee in solving this problem. I believe that Medicare's beneficiaries and America's taxpayers deserve no less.

Mr. GREENWOOD. I thank the gentleman for his comments and cooperation and support in this project and inform the chairman that it is our intent to have legislation included in an omnibus—whatever omnibus appropriations bill is finally adopted by the Congress that will fix this system soon.

The statement of the ranking member of the full committee has been entered into the record, and with that the chairman then turns to the ranking member of the Health Subcommittee for 5 minutes.

Mr. BROWN. I thank the chairman. I thank both Chairman Bili-rakis and Chairman Greenwood for holding these hearings.

A recent poll conducted by Pew Research Center told us that Americans are finding it difficult to reengage in their daily lives after the heart-breaking events of last week. We certainly didn't need a poll to tell us that. I think most people in this room are struggling, as all of us up here are, to regain our footing and return to their lives despite the anger and sense of loss that has paralyzed in some sense many of us. But I think most of us also feel it is time to get back to work.

Staggering prescription drug costs are still pushing retirees deeper into poverty. Forty-four million Americans are still uninsured, and that number pretty clearly is rising. The uncertain economic climate makes it more important than ever to fortify the Nation's core public programs, Medicare, Social Security, Medicaid, our public health infrastructure.

Our job today is to look at some shady dealings between drug companies and the Medicare program. The Medicare program and Medicare beneficiaries are being scammed to the tune of \$800 million annually. Some drug companies mark up their prices before reporting those prices to Medicare. What do the drug companies gain from this deception? They gain a higher volume of sales. What do doctors gain from this? They gain a healthy margin in the drugs they administer to Medicare beneficiaries. What do Medicare beneficiaries gain? They gain significantly higher out-of-pocket cost when the copayment is artificially inflated. Medicare pays more than it should, Medicare beneficiaries pay more than they should, and doctors not only receive higher reimbursements than they should, they have an incentive to overtreat patients. There is evidence that a few doctors actually take the bait and administer more medication than is necessary.

When you think about the type of drugs Medicare currently covers, chemotherapy, immunosuppressives, respiratory therapy drugs, other medications for serious, serious illness, it is truly disturbing to think that any doctor would compromise the Hippocratic oath in this manner. On the face of it, the so-called average wholesale price scam looks like a textbook case of fraud, waste and abuse. AWP is a bit like the Holy Roman Empire we learned about in school. The Holy Roman Empire to be sure was not holy, and it wasn't really Roman, and you could hardly call it an empire. It is the same with the average wholesale price. They aren't the average of anything, they certainly aren't wholesale, and, in fact, they aren't even prices. They are a marketing tool.

Unfortunately in some cases the excess Medicare spending appears to compensate for inadequate Medicare reimbursement. That makes the job of this subcommittee or both subcommittees and this committee more difficult. Not only do we have to figure out how much to pay for these drugs, we have to figure out how and how much to pay providers who are not receiving adequate reimbursement for administering these drugs.

But there are also opportunities here. When we look at how to pay appropriately for this limited set of prescription drugs, we should also think about how to pay appropriately for all prescription drugs. We can tell that the prices Medicare pays are artifi-

cially inflated across the board, in the majority of cases are artificially inflated, by comparing them to the prices other U.S. Purchasers, large HMOs, the VA, certain big hospitals that other U.S. Purchasers pay. We can tell that the drug prices that American consumers pay are artificially inflated by looking at the prices consumers in other countries, in other developed wealthy countries, pay.

Consumers, employers, and other purchasers in the United States pay two, three, sometimes four times more than their counterparts in every other developed country in the world for prescription drugs. As a Nation we are the worst equipped to weather artificially inflated drug prices. Every other developed country has universal health insurance. We have 44 million uninsured individuals under age 65. We have 12 million Medicare beneficiaries who have no prescription drug coverage.

Mr. Chairman, we have a lot of work to do. Thank you.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes for his opening statement the chairman of the Subcommittee on Health, Mr. Bilirakis.

Mr. BILIRAKIS. Thank you, Mr. Chairman. I, too, would like to thank you for raising and staying with this issue surrounding this current system of Medicare drug reimbursement which has resulted in this joint hearing. The Health Subcommittee has spent a considerable amount in this Congress examining how best to add a comprehensive prescription drug benefit to the Medicare program. This hearing builds off the work that began in the last Congress where we examined the reimbursements for the limited drug coverage currently available in the Medicare program.

I would like to welcome and thank our witnesses, including Tom Scully from CMS and Bill Scanlon from GAO. We rely on these government officials for factual information and detailed analyses. I also would like to welcome Mr. Zachary Bentley from my home State of Florida, the southern part, and I know your testimony, Mr. Bentley. All the witnesses will help inform the committee and the public about the issues regarding Medicare's current reimbursements to health care providers for certain drugs used to treat patients.

The Medicare program currently provides coverage for a small number of drugs, as we know, much too small, but a small number, limited principally to those that are administered incident to physicians' treatment or in conjunction with covered durable medical equipment such as inhalation drugs used with a nebulizer. Since at least 1992, Medicare has determined the appropriate reimbursement price for these covered drugs by referring to an industry trade publication known as the Red Book, which looks at what manufacturers purport to be the average wholesale price for their drugs. Since 1977, providers who administer these drugs to Medicare beneficiaries have been reimbursed for their cost at prices equal to AWP, average wholesale price, minus the 5 percent. Of this set amount, Medicare Part B covers 80 percent—this has all been said, I realize—while Medicare beneficiaries can be required to pay the remaining 20 percent as copayment.

Today's hearing will examine how Medicare's current reimbursement system for the relatively few drugs that are covered is costing

beneficiaries and taxpayers more than is necessary and maybe having an adverse impact on the health of some of our most vulnerable citizens.

I recently toured, Mr. Chairman, Clearwater Oncology Center in my Florida district, and I am sure we are all aware of what great work oncologists do and how important they are to us and just to all Americans. At the request of my constituent Dr. Marcus Chopart, I would like to admit this white paper prepared by U.S. Oncology, which is entitled Reimbursement Versus Reality, into the record and ask unanimous consent for that.

Mr. GREENWOOD. Without objection.

[The following was received for the record:]

#### REIMBURSEMENT VS. REALITY

A US ONCOLOGY DISCUSSION PAPER ON MEDICARE PAYMENTS FOR CANCER TREATMENT

##### *Introduction:*

Today, the Medicare program makes a significant and well-recognized overpayment for oncology drugs. The program also makes a nearly equivalent but less well-recognized underpayment for practice expenses associated with the delivery of cancer care. This paper is intended to discuss the causal factors and current experience of this practice expense underpayment. It is offered in the hope of furthering the public policy discussion and the cancer community's longstanding support for balanced reform, which will address Medicare's overpayment of drugs and underpayment of services. In this manner, the Medicare program will provide a stable source of adequate reimbursement for cancer care supplies and services and preserve patient access to community-based cancer services.

##### *Discussion:*

Medicare practice expense reimbursement for chemotherapy administration was established to accommodate a delivery system profile that no longer exists in the US. Whereas most chemotherapy was administered in hospital settings as recently as the late 1980s, Centers for Disease Control and Prevention (CDC) data currently indicate that more than 80 percent of all chemotherapy treatment encounters occur in non-hospital outpatient settings (freestanding oncology physicians' offices and community cancer centers). Reimbursement policy changes, managed care cost-saving pressure, patient preference, the advent of more effective ambulatory therapies, and the advanced capability of freestanding facilities to provide highly-complex care are the major causal factors that fueled the migration of patients from hospital to non-hospital settings.

This historical perspective is important because it helps to explain the flaws plaguing the Medicare program's practice expense reimbursement policy for cancer care. When the Resource-Based Relative Value Scale (RBRVS) was established in 1992, the Practice Expense (PE) components within the RBRVS were based upon historical "usual and customary" physician fee schedule systems that evolved at a time when most chemotherapy was administered in hospitals. As a result, reimbursement levels for the RBRVS codes relating to physicians' offices and other freestanding facilities were based on the few resources that were used in those settings during the period preceding the RBRVS implementation.

The evolution of cancer care and the resulting reimbursement discrepancy described above has long been recognized by Congress and HCFA/CMS. For example, after it became clear in the mid-1980s that chemotherapy was moving to freestanding facilities, Congress required the Secretary (in section 4055(d) of OBRA 1987) to study and report to Congress on possible Medicare reimbursement changes to more accurately reflect the costs associated with providing chemotherapy in physicians' offices. HCFA subsequently published a notice in the Federal Register that recognized that Medicare payment for chemotherapy administration may be inadequate:

"Changes in treatment methods and advances in technology now allow chemotherapy to be furnished to many patients in the physician's office, thus reducing the need for hospitalization to administer chemotherapy. Furnishing these services in the physician's office is more convenient for some patients and may provide other benefits as well.

“Current Medicare Part B payment rules for physicians’ services, however, may fail to compensate adequately for these services because the usual reasonable charge methodology may not fully recognize the overhead costs involved in these procedures. Some sources of additional costs include employment of nurse oncologists, special patient rooms, and safety equipment required because of the toxicity of the chemotherapeutic agents and safety procedures issued by the Occupational Safety and Health Administration.”

Unfortunately, this recognition has never been translated into more accurate Medicare reimbursement for cancer care services. As a result, inadequate and inaccurate payment levels have been utilized since the creation of RBRVS, with updates for inflation but without any significant revision, even though the locus of non-surgical cancer care has moved from hospital settings to freestanding physicians’ offices and community cancer centers.

In other words, the resource-based codes currently used by Medicare to reimburse for oncology practice expenses do not reflect the transfer of resources from hospitals to freestanding facilities and the additional costs that have arisen consistent with advances in and the complexity of today’s more effective treatment regimens. Put another way, hospital care and complex services moved to freestanding facilities—but Medicare’s practice expense reimbursement policy has never been significantly and continuously updated to reflect that fact.

*Summary Points:*

The implications of the above can be identified through examination of the many instances of shortfall which exist between the delivery and reimbursement of cancer care in freestanding facilities. The following bullet points summarize just a few of these:

- Today, nursing and pharmacy time comprise the principal components of the direct labor costs of oncology practice expenses (PEs). However, the allocation of values and minutes within the CPT codes does not match the actual cost and duration of nursing services and does not address pharmacist and pharmacy technician labor and related medical supplies and quality control processes. For example, CPT 96410 (first hour of chemotherapy infusion) does not adequately reimburse for the actual costs of the activities which currently fall under the definition of that code. In addition, activities which need to be performed in the care of a typical patient often exceed 96410’s 121 minute estimate of total nursing time. This is a commonplace problem in oncology due to:
  - The compromised physical and mental condition of many seniors with cancer,
  - The complex procedures integral to the care provided to all cancer patients undergoing chemotherapy treatment (for example: patient assessment prior to chemotherapy administration, evaluation of laboratory data such as blood counts and renal and liver functions, calculation of drug dosages based on body surface areas to prevent medication errors, insertion of intravenous or central venous catheter devices, continuous monitoring to address potential adverse reactions, a variety of assistive care activities, and hazardous materials preparation and disposal).
  - The amount of patient and family member training required due to the delivery of outpatient rather than inpatient care, the complexity of care provided, and the side effects and potential complications associated with multi-drug agent chemotherapy regimens,
  - The time-intensive nature of patient care-related follow-up and monitoring required due to the life threatening side effects and complications routinely experienced by cancer patients during a typical chemotherapy protocol, and
  - The recently-established standard of practice in which pharmacists and pharmacy technicians are utilized within cancer care facilities to enhance the safety of the drug administration process. As the recent Kansas City experience clearly demonstrates, on-site skilled pharmacy services are integral to the delivery of safe and effective cancer care.
- Medicare utilizes chemotherapy administration codes published in the AMA’s *Current Procedural Terminology* (CPT) manual but applies rules that differ from the CPT’s descriptions. For example:
  - Medicare only allows code 96408 (administration by push technique) to be reported once per day for a patient regardless of the number of drugs administered by push. Many treatment regimens require the administration of multiple drugs, however, some of the most common of which are vesicant. Drugs classified as vesicant are agents that will cause serious tissue damage (including potential loss of limb) if they leak into the tissues of the patient’s hand or arm; as a result of the potential for this serious complication, the administration of vesicant drugs requires prolonged one-on-one nursing care. As a re-

sult, caregivers routinely bear significant multiple push and specialized care costs that are not adequately reimbursed under current practice expense policy.

- CPT 90784 (intravenous push of therapeutic medication) is a code that was established to cover the costs of administering non-chemotherapy agents such as anti-nausea medications, anti-sensitivity drugs, and steroids. Despite the intention that code 90784 provide reimbursement for therapeutic agents and despite the fact that such agents are often a necessary component of a chemotherapy regimen, Medicare will not make a payment for 90784 activities that are undertaken on the same day as the infusion of a chemotherapeutic agent. CPT 96410 includes a general description of the service (first hour of chemotherapy administration). Based upon that description, CMS' Clinical Practice Expert Panel (CPEP) process has estimated a time allotment of 121 minutes, an allotment included in published Medicare payment policy. However, actual Medicare reimbursement does not currently cover 121 minutes of nursing time and instead provides for a payment level that covers just an estimated 20 percent of costs associated with 96410.
- Current Medicare practice expense reimbursement for oncology either does not take any account of a wide variety of activities which are common and integral to the delivery of cancer care in freestanding facilities or allocates significantly insufficient minutes and resources to them. For example:
  - Triage and patient/family education, which consumes an estimated 25-40 percent of a typical oncology nurse's day (versus the 15 minutes now allocated by Medicare) and involves frequent and lengthy phone interaction with the patient and/or the patient's family support person,
  - Tumor registry-related activities (required by most state health departments and managed by the Centers for Disease Control and Prevention),
  - Clinical research-related activities (recently approved for Medicare coverage but currently lacking any PE adjustments for the significant labor adjustments required due to the data intensive nature of the clinical research process),
  - On-site pharmacy-related activities (increasingly becoming the standard of practice due to the increasingly complex nature of new chemotherapy drugs and biotechnology agents and due to the necessity to free up oncology nurse time in light of the national shortage of trained nurses),
  - Biohazardous waste disposal (including federally-mandated disposal systems and required monitoring of disposal by specialized vendors in federally approved disposal sites), and
  - Financial counseling and financial aide assistance (requiring an estimated 10-20 percent of a typical oncology nurse's day due to the aggressive denial of benefit standards-of-practice within the insurance industry and by Medicare intermediaries).
- As a result of the scope of services that are not currently being reimbursed or that are inadequately reimbursed, oncology nurses estimate that a majority of their time is devoted to activities that are not currently "billable" (i.e. considered within the components of the various CPT-4 codes) under Medicare. Of those activities which can be billed today, the vast majority are reimbursed at levels that are far below the actual cost of undertaking them (at levels estimated to be less than 20 percent of actual costs reimbursed).
- Current Medicare practice expense reimbursement for oncology does not take into adequate account a wide variety of processes, supplies and equipment which are common, frequently mandated by federal law or regulation, and integral to freestanding facilities. For example:
  - Hepa-filter equipped hoods for admixture (to prevent exposure and contamination),
  - Safe-needle systems (to prevent caregiver needle sticks),
  - Biohazardous waste containers (to prevent exposure and contamination),
  - Reinforced gowns and gloves (to prevent exposure and contamination),
  - Specialized devices required to access implantable central venous ports to safely administer toxic chemotherapeutic agents and reduce the complications (especially life threatening infections) associated with frequently repeated intravenous drug administration processes,
  - Business and clinical record audits and internal reviews required to ensure compliance with billing regulations as recommended by the OIG Guidelines For Medical Practices, and
  - Business and clinical record audits required by the FDA, OIG, and Medicare intermediaries associated with standard of care procedures and drugs utilized in the clinical research process.

- In the late 1990s, Medicare practice expense components were made resource-based, a process which presented an opportunity for the inadequacy of drug administration payments to be addressed:
  - HCFA initially pursued an approach that would have increased payments to cover costs; the Agency adopted a “bottom up” approach under which clinical practice expert panels (CPEPs) were formed to estimate the staff time, supplies, and equipment used in each service.
  - Because the bottom up methodology would have resulted in significant shifts of Medicare payments among various specialties, however, legislation was enacted that postponed implementation of the resource-based practice expense components for one year and specified new criteria for HCFA to consider in adopting a methodology.
  - As a result, HCFA changed to a “top down” methodology, which resulted in the preservation of the status quo.
- On November 1, 2000, HCFA published the final rule for the FY 2001 physician fee schedule that also presented an opportunity for the inadequacy of drug administration payments to be addressed:
  - HCFA accepted and published recommendations made by the American Medical Society’s Relative Value Update Committee (RUC) and Practice Expense Advisory Committee (PEAC) for CPT codes 96408 and 96410. [42 CFR Parts 410 and 414, 65392-65393]
  - In its rule, HCFA stated “We will now use the RUC-recommended total times of 102 minutes of clinical staff time for CPT code 96408 and 121 minutes for CPT code 96410.” HCFA also posted a complete database on its website (<http://www.hcfa.gov/stats/resource.htm>) that provided dollar values (inclusive of direct and indirect expenses) for the updated codes, as follows:

Code	Published Value	Actual Value	Percent Difference
96408 .....	183.67	37.11	495%
96410 .....	267.05	59.684	47%

- Despite being accepted and published by HCFA in its final rule, the significant increases were not adopted into the Medicare program’s actual payment levels.
- For codes lacking a physician work value (such as all chemotherapy administration codes), HCFA adopted a methodology in which a special “zero work value pool” was created. HCFA has never published an explanation of this methodology, but the pool reportedly is assigned dollars based on the practice expenses per hour of the average physician, and non-physician time for each procedure is substituted for the physician time that would otherwise be used.
  - As a result of this methodology, Medicare payment amounts were kept at approximately the same levels as existed prior to the institution of the resource-based system (in fact, it has been suggested that HCFA selected this methodology to maintain the status quo in payment amounts).
- Medicare pays a “bad debt credit” to offset uncompensated care provided by hospital settings but does not currently have any provision for such a payment to freestanding facilities (which provide the majority of uncompensated chemotherapy services to Medicare beneficiaries who cannot meet their coinsurance obligation, among other needy patients).
  - According to the Medical Group Management Association (MGMA), the typical physician office setting experiences a non-collection rate equivalent to 7.5 percent of allowable reimbursement.
  - In many community-based cancer care facilities—where a large segment of the Medicare patient population is dependent upon Social Security as a main source of income—non-collection levels may be much higher than MGMA’s estimate.
- A number of activities and infrastructural resources are needed to operate an efficient and compliant oncology office. However, many of the costs associated with those activities and resources are not currently reimbursed. As a result, additional practice expense allotments or reasonable returns on services, products, and other resources are needed to: attract and retain staff (due to the inadequacy of current practice expense reimbursement); invest in facilities, therapy inventories, and required diagnosis and treatment technology; finance accounts receivable; invest in information and operational systems to meet NCI/FDA clinical trial research data requirements; retain outside compliance advisors and auditors; and meet HIPPA regulatory requirements.

*Conclusion:*

It is our hope that this information will be helpful as Congress and the Administration seek to address the disparity between typical, necessary practice expenses and the reimbursement currently provided under the Medicare program (and, as a consequence, by private payers). It is also our hope that a clear focus on the nature, complexity, resource intensity, and technological advances of community-based cancer care—as well as the reliance by the vast majority of Americans with cancer on care provided in community-based settings—will lead to an updating of Medicare practice expense reimbursement to accurately reflect the realities of cancer care delivery today.

Mr. BILIRAKIS. This will prove to be a lengthy hearing, and thus I am limiting my opening statements so we may get to the important testimony of the witnesses, who, again, I thank for their efforts and cooperation. Thank you, sir.

Mr. GREENWOOD. I thank the gentleman and thank him also for limiting his remarks. I will ask if the opening statements of the Members could be limited to 3 minutes, and all opening statements will be entered into the record.

The Chair recognizes for the opening statement the gentleman from New Jersey Mr. Pallone.

Mr. PALLONE. Thank you, Mr. Chairman, and I want to thank you both, you as the Oversight Chairman and also Mr. Bilirakis as the Health Subcommittee Chair for holding this hearing.

The issue on the table today critically analyzing the marketing practices of drug companies will show the immense amount of fraud perpetrated on the taxpayers and the senior citizens of this country. I along with all of my colleagues condemn practices that raid the Federal Treasury of at least \$800 million annually. Further, I am particularly outraged at the impact of this pervasive fraud on Medicare beneficiaries by massively increasing the dollars coming out of pocket to cover the drug costs of sick and dying seniors as a result of the 20 percent copay overcharges.

Mr. Chairman, the GAO, the HHS, inspector general, and some particularly well-informed whistleblowers will testify today and leave no doubt that this system is broken and that the people who can least afford the cost, our seniors, are the primary victims.

Let us take a look at the winners and losers in the way HCFA pays for the few outpatient drugs that Medicare covers under Part B. The winners are obvious. They are the brand name drug companies and some unscrupulous physicians that administer the chemotherapy and other infusion drugs in their offices. There have been some discussions that generic competition is the cause for the broken system, but make no mistake, it is not independent generics, but rather the brand name firms that are the root cause of this fraud.

The companies named publicly in news stories as having pled guilty to crimes are under active investigation. In addition, Mr. Chairman, the competition is not always among drugs that the FDA says are generic equivalents. The competition is also among brand name drug companies that go to great pains to claim that their products are not therapeutically interchangeable.

Documents which will be introduced at this hearing will show that the salesmen peddling these drugs were not arguing that their medicine was therapeutically superior to the competition, but rather the internal company documents make clear the field of battle

was who could misrepresent their prices more outrageously to Medicare so as to provide the fattest profit. There are some greedy doctors, of course, who pocket sums approaching a million dollars, and they are obviously making a lot of money; however, it is the drug companies' fraud that makes the money possible.

The Medicare reimbursement system is flawed, clearly, but no law, no regulation, no guideline issued by HCFA or any other government agency directed drug companies to commit fraud. Just because a system can be gamed doesn't provide any person or any firm with the right to defraud the government or their fellow citizens, and the proof of that is that not all drug companies played this game. Some chose to compete only on traditional terms, and I certainly commend them for that. Unfortunately, at least in segments of the market, the honest firms were the exception and not the rule, and I find that very tragic.

Thank you very much, Mr. Chairman.

Mr. GREENWOOD. I thank the gentleman and recognize the gentleman from Florida Mr. Stearns for his opening statement.

Mr. STEARNS. I thank the chairman, and I also want to thank Mr. Bilirakis for all the work he is doing on this hearing, too. And, of course, I want to thank Administrator Scully for coming here with Deputy Inspector Grob and Director Scanlon for their dedicated analysis. And perhaps this is a quagmire that they can help us out of by suggesting legislation, what we should do.

This is sort of an embarrassing thing to be here, this many people. Obviously when I see a lot of people like that, there are pocket-books involved here, but we have got to do something, and as Chairman Tauzin mentioned, we cannot sit here and let this continue. I almost think there is moral obligation to go back and try to rectify this. No one is talking about all the American citizens who have paid all this money and have paid too much, and it is out of their pockets, and it has gone in the wrong directions, and it is difficult to go back in retrospect and try to come back with something to rectify this but just move forward. Maybe that is all we can do.

I also want to thank Mr. Zachary Bentley from my State of Florida. I know it is a little difficult for him to come up here with airline travel, so I appreciate his efforts in coming up here.

This is a very thorny question, reimbursing for drugs. Who would have thought that when Medicare started, that you would actually be doing a lot of the caring for patients in outpatient clinics? I had the opportunity to visit and to tour an oncology center in my hometown of Campbell, Florida, and it is very satisfying to see patients cared for in this outpatient clinic. The drugs are administered by nurses and doctors, and these patients have their family right there. It is an informal situation, but all the while this is happening and they are administering these drugs and taking care of them, obviously the question they brought to my attention is that Medicare is overpaying for drugs, but underpays for services associated with the administration of therapies. So this is a very poor accounting practice.

It is immoral what we are doing. It is unsettling to patients, and many patients, as the chairman has pointed out, are paying 300 and 500 percent in their copayment. This cannot be tolerated, and,

Mr. Chairman, I commend you for your hearing today, and your commitment to do legislation is very important.

Finally, it is hoped that whatever drug reimbursement system is employed, it should not impose burdensome accounting requirements on the medical facilities and providers. So whatever we do, let us try to rectify the problem without creating another overlay of government upon government with some kind of accounting procedure. Remember, the caregivers who take care of patients with cancer and all these respiratory problems and devastating illnesses are healers. They are not bean counters. They don't want to spend the rest of their life filling out government forms to rectify this problem.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes the gentlelady from California Mrs. Capps.

Mrs. CAPPS. Thank you, Mr. Chairman.

Obviously for most of us our thoughts are elsewhere today. They are in New York, at the Pentagon, in the homes of the families across America who have lost loved ones in last week's terrible events. I think especially of Lisa Raines, so closely involved with many in this room today. Those events and their ramifications will certainly be with us for a long time, and clearly we need to spend significant time on our Nation's many responses to them.

But I am very pleased that at this time this committee is making an effort to continue its business. Although the attacks have changed many of our priorities, we still must address Medicare and Medicaid and other issues that may seem mundane in comparison.

So I want to direct my attention to the issue at hand. It is very disheartening to learn about efforts to take advantage of our Nation's seniors and America's taxpayers. And clearly if what we have been told is true, that is what has happened. Pharmaceutical companies have worked to increase their profits by artificially raising the Medicare reimbursement rates for certain prescription drugs, particularly oncology drugs. Sometimes this happens to the point where our beneficiary pays more in his or her copayment than it costs to buy the drugs outright. Clearly, given the current budget situation, Medicare cannot afford to be paying too much for the services and prescription drugs, and certainly our seniors are already too strapped to afford most of their prescription drugs. To take money from their already overextended pockets this way is terrible.

It is even worse that this is being done with something as important as oncology drugs. People suffering from cancer should not be the target of anyone trying to make a profit. Many provider groups are arguing that their reimbursement rates for the services they provide are too low, and they need the surplus payments to cover extra costs. It is true that reimbursement rates for certain services are too low. This is certainly true for oncology nursing, which I know from personal experience is essential to cancer treatment. In fact, last year I taped a message for a video about the importance of oncology nursing and nurses and the need to improve their rates of reimbursement. But I want to make it clear that just because these rates are too low does not mean it is all right for other rates to become too high.

Congress and the Centers for Medicare and Medicaid Services need to act now to end this practice. We need to make sure that Medicare is neither overpaying nor underpaying for any services. To do otherwise threatens the very stability of Medicare and the ability of our doctors to provide important health care. We must stop the gouging of our seniors and constituents by drug companies looking to gain a little market share.

Mr. Chairman, I am glad you are holding this hearing, and I look forward to working with you in the future.

Mr. GREENWOOD. The Chair thanks the gentlelady and recognizes the gentleman from Georgia Mr. Deal for an opening statement. Mr. Deal's not here.

Dr. Ganske for an opening statement.

Mr. GANSKE. Thank you, Mr. Chairman.

I think it is important to have this hearing. We need to look at the concept of the average wholesale price. In my mind the question is, is it the wrong concept for us to be using in terms of reimbursement, or is the information-gathering and the actual way that it is being implemented wrong, and does that need to be improved?

We have to remember that we are not just talking about Medicare, we are talking about Medicaid and also proposals to provide prescription drug coverage for Medicare recipients. I have a proposal, for instance, that would extend Medicaid coverage to the neediest, and so I think that—and the way the AWP has done is important. We need to address issues of potential fraud.

But I want to say this: This last Sunday I gave a speech at my church on September—about the events on September 11, and it was pretty emotional, but it was especially emotional for me because I sat next to my former district staff director, who has advanced lung cancer and is getting chemotherapy. And I will tell you, Mr. Chairman, it makes me rather angry to hear people sit up here and pontificate about the motives of the physicians who are taking care of Luke. What is medical necessity in his case? Some of the things that I have heard would indicate that we questioned the motives of the doctors who are taking care of him because they can't cure him, but they are giving him chemotherapy that may give him a couple extra months of life. I would ask my colleagues how much is that worth?

So let us get away from some of this rhetoric up here about the motives. Let us talk some of the facts. Here is a fact. When Luke goes in for chemotherapy, his doctor is paid \$62 for the administration of that chemotherapy. Just the cost of the nursing help is probably over \$100. We are not even talking about if he is a Medicare patient. We are not even talking about the cost of the overhead. It is likely that the cost for that physician to administer that type of chemotherapy for a Medicare patient, reimbursement by Medicare is less than one-half, maybe less than one-fourth of what the actual costs are, and that isn't even taking into consideration the amount of time for the personnel and the physicians involved with the multiple phone calls that chemotherapy patients put in to a physician's office.

So when we're talking about this threat, let us also talk about the threat in Medicare and the totally inadequate payment of Medicare services for this, because this is really important. If this

isn't addressed, then those Medicare patients ultimately will not get the type of care that they need, like my friend needs right now.

So let us look at fixing this AWP. Maybe it can be fixed. Maybe we can prevent some of the problems. But you know what? I'd have to say this. If a Medicare HMO negotiates a discount with a pharmaceutical company and thereby increases its profits, is that fraud? Should we be looking at that?

My suggestion is this: Why don't we get the actual data on the average wholesale price. Let us collect the slips and find out what the pharmaceuticals are actually charging and being paid. I would predict then that you will see, when you get a more accurate AWP, you'll see some changes in that, in those amounts, and you'll then get a more accurate index of what, for instance, the reimbursement truly ought to be for the physician services.

So, Mr. Chairman, I think it's a pretty important hearing, and I would just ask my colleagues to look at this in a rational way. Thank you.

Mr. GREENWOOD. The Chair thanks the gentleman and assures the gentleman that it is our intention to make sure that oncologists and all providers are adequately compensated—appropriately compensated, and, in fact, it will be the testimony of the General Accounting Office that will give us the facts that we need to determine what that reimbursement should be.

The Chair recognizes for an opening statement the gentleman from Texas Mr. Hall.

Mr. HALL. Mr. Chairman, thank you, and I think Mrs. Capps really hit the nail on the head when she talked about priorities, because we all have priorities, and I think it is great of this chairman and the ranking member to hold this hearing in the midst of all the anxieties that the people have all across this country.

This is very important, and I suppose if I could say anything to add to the opening statements that's been made, it would be that I'd like to see us come together, not slapping one another around, but to come together to solve these problems, Medicare, Medicaid, Social Security, the needs that the people have out there, and come together as closely as we're together after the President's speech last night on foreign affairs and offense and defense. That is what is really needed.

I'm very interested in the studies that have been made by GAO and CMS. I hope they're on current data on costs for physicians, particularly in chemotherapy, because in my family I have that problem, have had that problem to one very dear to me. We've all—we are all what our experiences are. But I think the very fact that we have all these empty seats here indicates that we are in a busy time, in an anxious time, and I thank you for having this hearing.

I support the hearing and the things that we're going to have here, and I'd make a request, if it has not already been made, that we be allowed to submit questions and leave them on the record to have their answers put into the record to where the rest of the Congress and the rest of the Nation might have the benefit of this hearing, and I yield back my time.

Mr. GREENWOOD. Without objection, questions posed by members of the committee will be included in the official record.

The Chair now recognizes the gentleman from Pennsylvania Mr. Pitts for his opening statement.

Mr. PITTS. Thank you, Mr. Chairman. I want to commend you and the staff and the whistleblowers for uncovering this serious abuse in the Medicare drug reimbursement system. The system deeply is in need of reform, and I want to thank you for holding this important hearing. I look forward to hearing from your distinguished witnesses today. Thank you. I yield back.

Mr. GREENWOOD. The Chair recognizes the gentleman Mr. Stupak for an opening statement.

Mr. STUPAK. Thank you, Mr. Chairman. I'll waive my opening statement. Just thanks for having this hearing. I look forward to the testimony we're going to hear today.

Mr. GREENWOOD. The Chair recognizes for an opening statement the gentleman from Georgia Mr. Norwood.

Mr. NORWOOD. Thank you, Mr. Chairman.

I wonder if I could identify who developed that slide while I'm beginning my opening statement so we can know who to talk to about it and try to understand it. But I do thank you for holding this important hearing this morning, and in the interest of time, I'm going to try to be brief.

It is clearly obvious that CMS needs to be in a responsible way paying for drug therapies that it does cover under Medicare, and if CMS is overpaying, then that problem needs to be corrected, period, now. If there is fraud in any way occurring with the AWP, that problem needs to be corrected now.

But the tone of the hearing is one in which I think we ought to be a little concerned about, and I'll spend my time talking about that. If our effort here is to try to find somebody to blame or scapegoats, we need to look, I believe, at other obvious points and the bigger picture that might be leading to some of these type of things.

I don't think it's a joke or anybody misunderstands that Medicare significantly underpays providers for many services, and you may not believe me or Dr. Ganske or Dr. Coburn or others who have been saying for years that is the case, and it is getting worse and worse, but it is the case, whether you believe us or not.

I don't think we need to pat ourselves on the back today and think we're making real progress on this one particular problem through this hearing, because the truth of the matter is we are still ignoring the fundamental problem of Medicare. Health care costs money, folks, and it is hard to understand sometimes why—when a patient is dying, perhaps the oncologist is continuing to inject that patient to buy them a few more months or weeks or make their life a little bit better.

Now, maybe we don't want to pay for that. Maybe we want to say that we don't want to pay for that, but let us be honest with our constituents. Let us be honest as a government entity. If we don't want to pay for that or can't, for pity sakes, stand up and say so. Don't try to find a scapegoat to blame.

Now, I don't understand the slide in the back of the room. I have a hunch the implication there is that, for example, Leucovorin costs \$1.25, and isn't it absolutely awful that the provider might be charging \$42 to use that injection? How could he possibly charge

so much money when it only costs \$1.25? Well, how about extending that slide all the way out over to here and show the real cost rather than to imply that one of our oncologists is just trying to rip you off. That is all it is. The poor government is getting beaten up by the medical profession because they would dare charge \$42 for a chemical that costs \$1.25. Now, I don't know if \$1.25 is the right cost or not, but I do absolutely know that slide is fraudulent. It is set up there to imply that somebody is ripping somebody off. Yet it ignores all the other costs that Dr. Ganske started to begin to talk about that is inherent in the price of giving that injection.

Now, if our staff is going to present to us information, I would kindly recommend that they present to us factual information and let us get at the truth, not have a witch hunt.

Now, Mr. Scully, you're here. We're going to talk to you about it. If there is fraud going on, get after it. If there are doctors absolutely cheating the system, get after them. But let us be honest about what we are discussing in a government program that year after year after year keeps trying to salvage the problem by paying people less than it costs to deliver services. Maybe we can't change that, but for pity sakes, let us be honest about that with the American people.

I wasn't as brief as I intended, Mr. Chairman. I'm sorry. I yield back the balance of my time.

Mr. GREENWOOD. The Chair thanks the gentleman. We'll deduct that from his round of questioning.

I'll simply indicate to the gentleman that we will recognize that many providers are underpaid. If we can recoup this billion dollars that is being wasted on underpayment for drugs, we'll probably have more than sufficient funds to pay a whole lot of providers.

The Chair recognizes for an opening statement the gentleman from Wisconsin Mr. Barrett.

Mr. BARRETT. Thank you, Mr. Chairman. Thank you for chairing this important meeting.

I agree with the previous speaker that we shouldn't be looking for a scapegoat, but I think at the same time we have a very serious responsibility to make sure that the taxpayers in this country are treated fairly, and according to the information that I have seen in fiscal year 2000, according to the Office of the Inspector General, Medicare could have saved between \$887 million and \$1.9 billion by paying prices that other government to nongovernment purchasers were paying. These amounts range from 17 to 32 percent to the total \$5 billion Part B costs to the government, and the recipients paying the bills.

So we do have an obligation, and we're not just talking about chump change here. This is a large amount of money, and it is our responsibility, I believe, to hold hearings like this to find out exactly what the problem is. So I, again, applaud you, Mr. Chairman, for holding the hearing.

On another note, I know Mr. Scully will be testifying, and I just want to highlight an issue that I think that we also have to address, which is not 100 percent on point, but there is a Federal barrier right now which prevents safety net hospitals from negotiating better prices on in-patient pharmaceuticals. There is an unreasonably narrow interpretation by CMS of a Medicaid provision passed

by Congress to facilitate free market negotiations between drug manufacturers and safety net providers. We need to make it possible for safety net providers to negotiate better prices on in-patient and out-patient drugs, and I hope to explore that further, and I would yield back the balance of my time.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes for his opening statement the gentleman from Michigan Mr. Upton.

Mr. UPTON. Thank you, Mr. Chairman, and at the same time, I, too, will ask unanimous consent to put my entire statement into the record.

I just would like to add, we do need reform in the system. It appears to be broken in lots of different ways. We need to help both the beneficiaries as well as the taxpayers. We need to make sure that the providers are adequately compensated in a fair way to make their expenses as well.

We have a good task ahead of us. I welcome the hearing on the debate this morning, this afternoon, and yield back.

[The prepared statement of Hon. Fred Upton follows:]

PREPARED STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM  
THE STATE OF MICHIGAN

Mr. Chairman, thank you for calling today's hearing on Medicare's system for reimbursing prescription drugs administered in physicians' offices and certain other settings. As the title of the hearing indicates, the current system serves neither Medicare patients nor the taxpayers well.

What our committee investigators and the GAO have uncovered is not pretty and reflects badly on everyone involved. Medicare's reimbursement system is being used as a tool in the intense competition for drug market share, leading drug manufacturers to overstate—sometimes grossly overstate—the average wholesale prices for their drugs. The often substantial differences between what Medicare will pay for drugs and what the drugs actually cost physicians may be influencing prescribing practices. And Medicare patients—already grappling with the ravages of cancer or other terrible diseases are having their pockets picked—paying twenty percent of sometimes grossly inflated Medicare prices rather than the often much lower actual cost of the drug the doctors are using to treat them. Then they pay again when Medicare premiums rise in response to rising program costs. And the taxpayers, who foot 75 percent of the program's costs, are having their pockets picked as well.

Mr. Chairman, I think all of us will agree today that we need to act quickly to fix the system in the interests of both Medicare beneficiaries and taxpayers.

I hope that today's hearing will give us the information we need to do it right—and the impetus we need to do it quickly. We need to figure out a way to get real data on real acquisition costs so Medicare payments can be adjusted to reflect reality. At the same time, to ensure continued access to care in community-based settings, we need to fix portions of the physician fee schedule to ensure that the true costs of administering these drugs are reimbursed. In short, we need to give CMS the tools it needs, legislatively and administratively, to do its job right and to protect some of the sickest and most vulnerable of Medicare patients.

Mr. GREENWOOD. The Chair thanks the gentleman and turns for an opening statement to the gentleman from Indiana Mr. Buyer.

Mr. BUYER. Thank you for the hearing, and I ask unanimous consent that my statement be placed in the record, and I would also be hopeful—I'm most hopeful that we will not try to demonize those who are dedicated to saving life, whether it be our health care providers or the those of whom manufacture these great drugs that help extend life. I yield back my time.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes for an opening statement the gentleman Mr. Bass from New Hampshire.

Mr. BASS. Thank you, Mr. Chairman.

It is clear this is not a simple problem. It will not demand a simple conclusion. I appreciate the two subcommittee chairmen holding this very important hearing, and I'll yield back.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes for an opening statement the gentleman from Texas Mr. Barton.

Mr. BARTON. Thank you, Mr. Chairman, and Chairman, both of you, for holding this joint hearing. Let the record show they come to hearings other than energy hearings, that I'm on this subcommittee.

I was visited yesterday in my office by a pharmaceutical chemotherapy company located in my district. They had done some mathematical analysis, financial analysis, not as extensive as what our subcommittees have done, and showed that just based on their review, there was almost a billion dollars that could be saved in the numbers that they looked at and the drugs that they were prescribing, that others were. So I'm going to have to be convinced that the current system is worth saving before I agree to save it.

If I had to vote today, I would vote to say that physicians could not prescribe and treat cancer patients. They can choose one or the other, but they can't do both, because it seems to me that the system that we have today is broken. We can't fix it. So we need to change it. So I'm going to lock forward to the testimony, but put me down as a Doubting Thomas that the current system is worth saving. And with that I yield back the balance of my time.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes for his opening statement the gentleman from Oklahoma Mr. Largent.

Mr. LARGENT. Mr. Chairman, in the interest of time, I want to submit my full statement for the record, and I'll yield back my time.

Mr. GREENWOOD. The Chair thanks the gentleman.

Mr. GREENWOOD. The gentleman from North Carolina for an opening statement, Mr. Burr.

Mr. BURR. Mr. Chairman, let me thank you for this hearing.

Mr. Chairman, every time we look at health care, we find a more difficult animal than sometimes on the surface we think it is. I think what we're looking at today is, in fact, very complicated. I think the important thing for Members to remember is that over the years it has been, in fact, this body that legislates much of what we do in health care. We respond to providers, we respond to patients, and hopefully sometimes we respond to need, the needs that exist in the delivery systems that we have some jurisdiction on.

We seldom get it exactly right. Most of the time we do get some things wrong, and, yes, in the last 7 years with the leadership changes, we have gotten some things wrong. But one thing that I have learned as a member of this committee as we talk about health care policy is that, one, we always have to strive to do a little bit better; and, two, we also have to be very cautious as we make change that we don't make things worse, that we look outside of the area that is our focus to make sure that changes that

we make don't adversely affect other areas of the health care delivery system.

I believe that we'll hear a lot of information today. I as one will take that information and try to put it through that test of how do we make it a little bit better. How do we make sure that we don't adversely affect other areas by not just the actions of this committee potentially in the future, but by some of the questions and some of the documents that, in fact, we put on the record, because I think, as we all know, throughout the health care system, whether you're in a hospital or whether you're in a provider's office today, your legal counsel watches what Congress says and what we do and eventually what we pass. And all of it to some degree is interpreted the same way when lawyers look at liability, and my hope is that Members will remember that as they ask questions, that they make sure that they clarify everything, and that in the end we do something that addresses exactly the problem that we're trying to get to, a faulty average wholesale price for pharmaceuticals in this country. If there are other areas we need to address, I note that this committee will have the will and the patience to do it.

Mr. Chairman, thank you for your time, and I yield back.

Mr. GREENWOOD. The Chair thanks the gentleman.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. ROBERT L. EHRLICH, JR., A REPRESENTATIVE IN  
CONGRESS FROM THE STATE OF MARYLAND

Mr. Chairman, thank you for holding this important hearing on legislative measures to address the Medicare reimbursement for pharmaceuticals. As you know, Medicare drug reimbursement levels affect millions of Americans who face a variety of serious illnesses.

As we will hear today from the GAO testimony and others, our already-strapped Medicare program, which pays for a limited number of critical drug therapies, overpays for the costs of these drugs. For instance, the Committee notes that 24 highly used drugs may be resulting in a Medicare overpayment of at least \$750 million annually. I am eager to hear the testimony before us today to learn more about this overpayment and consider ways to save the Medicare program—and Medicare beneficiaries who pay co-payments on these inflated values—a considerable amount of money.

While it is crucial to address the overpayment calculation for these drugs, I also see the other side of the argument. As I learned during the August District Work Period, providers of care depend upon these overpayments to provide critical care to their patients. As we will also hear today, Oncology treatment facilities represent the front line of defense for nearly 80% of cancer patients in our country.

Many in the cancer community acknowledge that the Medicare program employs a flawed reimbursement structure which *overpays* them for drugs. At the same time, however, they argue that Medicare also *underpays* for many services. For example, Medicare does not adequately support the critical role played by oncology nurses in the care of seniors and people with disabilities. In visiting an Oncology treatment facility in my district recently, I saw first-hand that preserving patient access to cancer care may only be achieved by simultaneously fixing Medicare's flawed reimbursement of cancer drugs and cancer services. Such serious flaws have forced these caregivers to engage in a form of "cost shifting" in which they use drug overpayments to offset Medicare's underpayment for the treatment services provided to beneficiaries. This is source of great uncertainty for seniors with cancer and places significant pressures on the professional caregivers who treat them. Given these two sides of the argument—with patients in the middle simply seeking quality care—I am eager to review the testimony of our witnesses and hope that we move forward to reform Medicare appropriately with the best interests of patients in mind. Mr. Chairman, I realize your deep concern about these issues as well and thank you for your leadership. I look forward to our witnesses' testimony and to working with you and our colleagues to ensure patient access to high quality care.

PREPARED STATEMENT OF HON. ELIOT ENGEL, A REPRESENTATIVE IN CONGRESS FROM  
THE STATE OF NEW YORK

Mr. Chairman, let me first express my profound sadness over the events of last week and extend my sincerest sympathy to the families of all the victims. But we must continue the business of the people. Today's hearing is focusing on how Medicare reimburses for drugs. It is apparent that it is a complex problem that affects many different areas, from patients, to physicians, to drug companies. Any proposed fix must consider the ramifications for all of these groups, however, the interests of Medicare recipients must be our top priority.

Congress must consider any proposed fix carefully. There have been several attempts to address this issue, which have either failed to become law or failed when they became law and were repealed. The goal that we must keep in mind here is that seniors receive safe, effective, low-cost care. In order to achieve that end, providers must be adequately reimbursed for drugs and the services they provide but fraud and abuse must be rooted out. In the past, Congress has fallen back on AWP (average wholesale price) when providers have said that they were not being reimbursed for their costs. Instead of considering new reimbursement policies, AWP was used to cover these costs. Now, this money may be taken away and providers will be left with inadequate reimbursements for their services. Clearly we must be sure to consider these circumstances.

There is no doubt that there is fraud and abuse because of AWP. I think we do need to fix this problem, but we need to make it better, not worse. I have introduced legislation to address one of the major problems with home infusion therapy. My bill, HR 2750, the Medicare Home Infusion Therapy Act, addresses the particular problems associated with home infusion therapy. Medicare's reimbursement policy for home infusion therapy is simply outdated. Modern medicine has made the administration of many drugs safe and effective in the home. However, because of ludicrous reimbursement provisions seniors are forced to stay in hospitals or trek to physicians offices on a daily basis to receive their treatment. In many cases, this treatment can be conducted in the home safely and at a fraction of the cost. To address this issue, HR 2750 directs the Secretary of Health and Human Services to set up a fee schedule for drug reimbursements and provider reimbursements that would ensure adequate and fair payments to providers. I feel that this legislation appropriately addresses the needs of seniors and providers and could serve as a model for a broader approach to the problems with AWP. I urge this Committee to examine this legislation closely and I also ask you, Mr. Scully, to work with me on this issue.

I want to thank all of our witnesses for attending this hearing today under such difficult circumstances. I look forward to hearing your testimony.

PREPARED STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM  
THE STATE OF TEXAS

Thank you Mr. Chairman for holding this hearing on Medicare's reimbursement system for oncology treatments.

In light of last week's events, it is difficult to get too worked up about issues like Medicare reimbursements and practice expenses.

But the truth is that we must continue to do our job in Washington, and as members of this committee, we must continue to improve our Medicare system for beneficiaries and providers.

This issue is an important one. Each day, 3,400 Americans learn that they have cancer. Every minute, another American dies from some form of this disease.

Cancer costs our country more than \$107 billion each year.

And with more than 60 percent of all cancers being diagnosed in individuals over age 55, the Medicare programs is bearing a significant burden for treating cancer patients.

When the Medicare reimbursement system was first developed, most cancer patients went to the hospital to receive treatment.

But nowadays, eighty-five percent of these cancer patients are receiving their treatment at out-patient cancer centers.

Our reimbursement system does not reflect the changing world of cancer treatment.

Medicare's reimbursement system for cancer drugs is based on an artificial average wholesale price or (AWP).

As our witnesses will testify, however, this AWP is dramatically inflated for cancer drugs, causing the Medicare program and its beneficiaries to pay exorbitant costs for their life-saving cancer therapies.

Medicare reimburses for 95% of the AWP for oncology drugs.

But, because the AWP does not actually reflect the costs of oncology drugs, physicians are being reimbursed for considerably more than they are paying.

As a result, physicians could be prescribing drugs based on how much they'll profit from them.

There are allegations that physicians won't prescribe a newer, more effective drug, because they don't profit enough.

Now oncologists, like most other Medicare providers, are underpaid for their practice expenses.

As the GAO will testify, oncologists are underpaid by as much as 15%. They use the windfall from the AWP to make up for the underpayment from practice expense.

This system is bad for patients, is wasteful, and is poor public policy.

There is no question on either side of this debate that the current system is broken.

But we must be careful to repair it in a way that does not endanger cancer patients.

We were all troubled by recent media reports where a pharmacist in Kansas was adulterating chemotherapy drugs, reducing their potency, and endangering the lives of cancer patients.

We must ensure the integrity and quality of our cancer treatment system.

But the reimbursement system we have in place must be changed.

It encourages dishonest behavior by both the pharmaceutical manufacturers and the oncologists.

It results in higher costs for both the program and the beneficiaries—patients who are probably facing the most daunting health crisis of their lives.

But whatever solution we craft over the coming months, we must ensure that all Medicare beneficiaries have access to the life saving cancer therapies that they need.

I look forward to the testimony of our witnesses, and I yield back the balance of my time.

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PREPARED STATEMENT OF HON. BOBBY L. RUSH, A REPRESENTATIVE IN CONGRESS  
FROM THE STATE OF ILLINOIS

Mr. Chairmen, I want to express my thanks to both of the Chairmen for holding this very important joint hearing on the reimbursement system for prescription drugs under the Medicare Part B program. While the Part B prescription drug program is a relatively small component of universe of prescription drugs used by seniors and others, it is, nonetheless, of critical importance to its users.

The Part B program covers those drugs used with durable medical equipment (DME) or infusion devices, and the host of drugs administered in the treatment of cancer, hemophilia, organ transplantation, emphysema, asthma, kidney dialysis, AIDS, and pain management therapies which are administered on an out-patient basis or in home settings. Many Medicare beneficiaries rely on these life-giving medications and we must ensure their availability and affordability.

Since the beginning of the Medicare Part B program for drug reimbursements, the cost of medications for beneficiaries under this program has grown significantly. Current estimates are that the cost of drug reimbursements has doubled in the last five years.

I am particularly concerned about the special needs of some of the users of these drugs, and have a number of questions about the coverage provided. For example, in hemophiliacs, what is the difference in cost between home infusion and hospital treatment for a bleeding incident?

I look forward to hearing the testimony of the distinguished panel of witnesses and to getting the answers to these, and many other questions regarding the reimbursement rates and processes under Medicare Part B program.

Thank you.

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PREPARED STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS  
FROM THE STATE OF MICHIGAN

Chairman Greenwood and Chairman Bilirakis, thank you for convening this hearing on Medicare's payment policy for prescription drugs. I realize that this hearing may not seem terribly important in light of the tragedy that struck our Nation on September 11th. The victims of these horrific attacks, their families, friends, and coworkers, and the security and safety of the American people are all at the forefront of our minds.

Yet in a time when government resources may be needed for purposes none of us could have imagined two weeks ago, we have an added responsibility to ensure that more routine government expenditures are not wasteful. This hearing concerns improper and excessive payments on behalf of the Medicare program. As stewards of Medicare, the Committee cannot and should not allow this practice of overpayments for prescription drugs to continue.

However, before we rush to fix the problem with legislation, we must ensure that any solution will do nothing to harm the patients who need these drugs. We must also be conscious of the impact any change we consider would have on the overall Medicare reimbursement system and other health care payers.

Medicare pays for prescription drugs on an outpatient basis in limited circumstances. One of these circumstances occurs when drugs are administered by a physician, oftentimes during the treatment of cancer. Medicare's reimbursement formula is set at 95 percent of the drug's average wholesale price, or "AWP." The problem with this formula is that AWP is an artificial number reported by the drug manufacturer. In fact, some drug manufacturers deliberately inflate the AWP that they report in order to make the drug more attractive to physicians. The results of this dubious behavior are higher copayments for seniors, an incentive for patients to receive wrong or unnecessary drugs, and waste to the Medicare program.

Congress has been aware of the problem with the current formula for many years. Today, however, the stakes are higher, because any solution we create could have a far-reaching effect on the senior citizens of this country. This Committee will be considering a broad prescription drug benefit in Medicare. It is crucial that the Committee focus on developing a new reimbursement formula that is accurate and workable, based upon a benchmark price that cannot be manipulated.

At today's hearing, some groups will testify that these outrageous overpayments for prescription drugs are necessary to make up for Medicare's under-payments for administering them. In correcting the drug reimbursement formula, the Committee should carefully examine this issue. We certainly do not want to create a situation where patients who need these drugs cannot find the drugs or a physician to administer them.

However, the primary issue before us today is that of prescription drug pricing. Billions of dollars have already been wasted—dollars that could have been spent providing broader prescription drug coverage to seniors. We have a duty to make sure that this practice stops, and to concentrate on creating a Medicare drug benefit where seniors are protected from price-gouging incentives.

Mr. GREENWOOD. The Chair now calls forward our first panel: Mr. William J. Scanlon, the Director of Health Care Issues for the General Accounting Office; the honorable George Grob, Deputy Inspector General, Department of Health and Human Services; and Mr. Zachary Bentley, the President of Ven-A-Care, Inc.

Thank you, gentlemen, for your presence today. This is a joint hearing between the Energy and Commerce Subcommittee on Oversight and Investigations as well as the Subcommittee on Health. The Oversight and Investigation Subcommittee is an investigative subcommittee, and as such we've had the practice of taking testimony under oath. Do any of you object to testifying under oath?

Seeing no such objection, the Chair then advises each of you that under the rules of the House and the rules of the committee, you are entitled to be advised by counsel. Do any of you desire to be advised by counsel during your testimony today?

Seeing no such request, in that case, would you please rise and raise your right hand, and I will swear you in.

[Witnesses sworn.]

Mr. GREENWOOD. Thank you. You are now under oath, and we will recognize first Mr. Scanlon for his 5-minute opening statement. Welcome, sir.

**TESTIMONY OF WILLIAM J. SCANLON, DIRECTOR, HEALTH CARE ISSUES, GENERAL ACCOUNTING OFFICE; GEORGE F. GROB, DEPUTY INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND ZACHARY T. BENTLEY, PRESIDENT, VEN-A-CARE, INC.**

Thank you very much, Mr. Chairman, and members of the subcommittees. I'm pleased to be here today to discuss this important issue and wish to share with you some of the work that we've been doing on the payment by Medicare for prescription drug coverage—the prescription drugs that it covers. We are releasing today a study that was requested in the Beneficiary Improvements and Protection Act on Medicare's pricing of these drugs and will soon release a related study on payments for drug administration services under Medicare's physician fee schedule.

Today I'd like to provide highlights of these two studies, both of which underscore the need for payment method modifications. Our drug pricing study's findings echo those of the Inspector General, the Justice Department, CMS and this committee's. All reveal that Medicare's method, as we've heard, for establishing drug payments is flawed. Simply put, tying Medicare's drug payment to AWP is a recipe for inflation and excess payments.

Even though AWP is often labeled a retail or sticker price, it's not even that. A price is what a purchaser pays for a product. AWP is closer to just a number that manufacturers can specify without rules or criteria, a number not constrained by the need to have a purchaser willing to pay it.

Like the Inspector General, we found that in 2001, wholesalers' catalog prices that would be available to any physician or pharmacy or supplier involved sizable discounts from the AWP. These conservative estimates of providers' acquisition costs indicated that discounts on physician-billed drugs, mostly chemotherapy drugs, ranged from 13 to 34 percent on most drugs and in some cases were even higher. Discounts on two inhalation therapy drugs that account for three-quarters of all the drugs billed to Medicare are startling: 78 percent for one and 85 percent off of AWP for the other.

Medicare's troubling experience in terms of drug pricing is often contrasted with that of the Veterans Administration. As the VA is essentially a health care provider and not a third-party payer like Medicare, its approach cannot simply be transferred to the Medicare program, but key elements can be emulated.

The VA uses the leverage of its and other Federal purchasers' volume to secure prices that are similar to those of other volume purchasers' market prices that someone actually pays. To accomplish this, it uses its leverage to get verifiable data on actual market transactions to establish price schedules. Furthermore, for selected drugs, it has consolidated purchasing power even more and used competition to secure even lower prices.

CMS is in a similar position in that it has available to it comparable information on market prices through the Medicare drug rebate program. We are recommending that CMS assess how it can use those data to ensure that Medicare's payments more closely reflect market prices and to explore how competitive procurements might be effectively used.

Let me turn now to the issue of payments for drug administration. As has been indicated clearly, there is widespread agreement in terms of drug pricing. Our findings are not controversial. However, providers have indicated that underpayment in terms of drug administration needs to be made up for by overpayments in the drug purchase area.

Our second report looks at payments for drug administration under the physician fee schedule, which include the bulk of chemotherapy administration services provided by oncologists.

In the past, we have examined the then-named HCFA's development of the resource-based practice expense component of physicians' fees. That is the part of physician fees meant to reflect the cost of operating a practice, like nursing and administrative staff, equipment, rent and utilities. We concluded then that the Agency's basic method of computing these fees was sound. It achieves the goal laid out by the Congress; that is, to stop having the money Medicare pays physicians distributed according to what physicians historically charge for their services, and to have that money distributed according to the relative amounts of resources needed to provide each service.

The implementation of the revised fee schedule, though, has been controversial. Since Medicare payments in the aggregate were deemed adequate, the Congress required that the new fees be budget-neutral. Then if one specialty's fees increased on average, some others would have to decline. Such redistributions have occurred, and some are quite significant. Oncology is one of the specialties that gain under the new fee schedule. Its practice expense payments are 8 percent higher than they would have been if the prior method of setting fees stayed in place. However, that does not mean that we do not believe there is a problem in the way fees for services, like chemotherapy administration by nurses, are calculated.

HCFA modified its basic method in computing payments for services delivered without direct physician involvement, which include chemotherapy administration as well as some services provided by other specialties. The modifications were intended to correct for perceived low payments for these services, and while they did increase payments for some, they lowered them for many others. Moreover, the modifications increased payments on average for services that did involve physicians directly. Oncology payments were more affected by these modifications, because their services not involving direct physician participation constitute a bigger share of their billings than other services. These services for oncologists are about one-third of their billings compared to 5 percent for all physicians.

The payments for nonphysician chemotherapy administration are on average 15 percent lower than if HCFA used this basic method. On the other hand, practice expense payments for services provided by oncologists themselves are 1 percent higher because of these changes. Using the basic method, which we believe is correct, for all services would increase practice expense payments to oncologists by 6 percent.

We don't think that the HCFA's adjustments, as I've indicated, were appropriate, and our study will recommend that they use the

basic methodology—that CMS use the basic methodology to determine practice expense payments for all services.

Oncologists have raised other concerns about the physician fee schedule, including the representativeness of data used to estimate these practice expenses and whether the data reflects current practices in delivering services.

We are currently conducting another study to determine how CMS can improve and update the information used to estimate practice expenses; however, what impact improved data may have on payments is uncertain. Payments are based on the differences in expenses of one specialty compared to another. Some of the data concerns raised by oncologists may apply equally well to other specialties so that additional and many current data may reveal that the relative cost of different specialty services would only change modestly.

Overall, let me say in conclusion, we believe that it should be a principle of Medicare payment policy to pay for each service appropriately and not to rely on overpayments for some to offset inadequate payments for others. An efficiently operated Medicare program needs payments that reflect market prices so that it benefits from the discipline imposed by other payers. It also needs to judiciously use the buying power associated with its size to secure even greater efficiencies, though that must be balanced with its responsibilities to assure access for beneficiaries and to treat providers fairly.

Thank you very much, Mr. Chairman. I'll answer any questions you have.

[The prepared statement of William J. Scanlon follows:]

PREPARED STATEMENT OF WILLIAM J. SCANLON, DIRECTOR, HEALTH CARE ISSUES,  
UNITED STATES GENERAL ACCOUNTING OFFICE

Messrs. Chairmen and Members of the Subcommittees: I am pleased to be here as you discuss the pricing of Medicare's part B-covered prescription drugs. The pricing of these drugs—largely drugs that cannot be administered by patients themselves—has been under scrutiny for several years. Most of the part B drugs with the highest Medicare payments and billing volume fall into three categories: those that are billed for by physicians and typically provided in a physician office setting (such as chemotherapy drugs),<sup>1</sup> those that are billed for by pharmacy suppliers and administered through a durable medical equipment (DME) item (such as a respiratory drug given in conjunction with a nebulizer<sup>2</sup>), and those that are also billed by pharmacy suppliers but are patient-administered and covered explicitly by statute.<sup>3</sup> Studies by the Department of Justice, the Department of Health and Human Services' (HHS) Office of the Inspector General (OIG), and the House Committee on Commerce show that Medicare's payment for these drugs in some cases is significantly higher than the actual costs to the physicians and other providers who bill Medicare for these products.

In September 2000, the Health Care Financing Administration (HCFA)—now the Centers for Medicare and Medicaid Services (CMS)<sup>4</sup>—took steps to reduce Medicare's payment for part B-covered drugs by authorizing Medicare carriers, the contractors that pay part B claims, to use prices obtained in the Justice Department investigations of providers' drug acquisition costs. HCFA retracted this authority in November 2000 following concerns raised by providers. In December 2000, as part

<sup>1</sup> In the case of chemotherapy drugs, the common practice is for a nurse to provide the services to administer the drug and for the physician to bill Medicare accordingly.

<sup>2</sup> A nebulizer is a device driven by a compressed air machine. It allows the patient to take medicine in the form of a mist (wet aerosol).

<sup>3</sup> Medicare-covered drugs and biologicals that can be self-administered include such drugs as blood clotting factors and some oral drugs used in association with cancer treatment and immunosuppressive therapy.

<sup>4</sup> Our statement refers to HCFA when discussing actions it took under that name.

of recent Medicare legislation,<sup>5</sup> the Congress asked us to study Medicare's payments for part B-covered drugs and make recommendations for pricing methodology refinements. We have reported our findings and made recommendations, as mandated, today.<sup>6</sup>

My remarks today will focus on (1) Medicare payment policies to cover part B-covered drug costs and costs of administering the drugs and (2) key features of other payers' reimbursement policies that suggest opportunities to improve the appropriateness of Medicare's payments. My comments are based primarily on our study of Medicare payments for part B-covered drugs and a forthcoming study of physicians' practice expense payments under Medicare's fee schedule.

In summary, our study shows that Medicare's method for establishing drug payments is flawed. Medicare pays 95 percent of the average wholesale price (AWP), which, despite its name, may be neither an average nor what wholesalers charge. It is a price that manufacturers derive using their own criteria; there are no requirements or conventions that AWP reflect the price of any actual sale of drugs by a manufacturer. Manufacturers report AWP to organizations that publish them in drug price compendia, and Medicare carriers that pay claims for part B drugs base providers' payments on the published AWP.

We found that, in 2001, widely available prices at which providers could purchase drugs were substantially below AWP, on which Medicare payments are based. For both physician-billed drugs and pharmacy supplier-billed drugs, Medicare payments often far exceeded widely available prices. Despite concerns about what discounts may be available to smaller-volume purchasers, physicians who billed Medicare for low volumes of drugs reported receiving discounts from AWP, for most drugs, that were similar to or greater than those afforded by the widely available prices we documented.

Physicians and pharmacy suppliers contend that the excess payments for covered drugs are necessary to offset what they claim to be inappropriately low or no Medicare payments for services related to the administration or delivery of these drugs. For administering physician-billed drugs, Medicare makes explicit payments under the physician fee schedule. Our forthcoming review of practice expense payments under the fee schedule will make several points regarding oncologists' payments. It will show that Medicare's payments to these specialists were 8 percent higher than they would have been if the program's prior payment method had remained in place and will show that oncologists' payments relative to their estimated practice expenses were close to the average for all specialists. However, we will also show that HCFA made questionable modifications to its basic method of setting practice expense payments, which resulted in lowering the average fees paid for the administration of drugs by physicians' staffs.

For delivering pharmacy supplier-billed drugs, Medicare's payment policies are uneven. Pharmacy suppliers billing Medicare receive a dispensing fee for one drug type—inhalation therapy drugs—but there are no similar payments for other DME-administered or oral drugs. However, Medicare pays DME suppliers for the rental or purchase of equipment and supplies, and long-standing problems in the program's payments for these items may result in overpayments that implicitly compensate for some service delivery costs not covered.

Other payers and purchasers, such as health plans and the Department of Veterans Affairs (VA), employ different approaches in paying for or purchasing drugs that may be instructive for Medicare. In general, they make use of the leverage from their volume and competition to secure better prices. The federal purchasers, furthermore, use that leverage to secure verifiable data on actual market transactions to establish their price schedules. Private payers' practices—such as negotiating prices that result in selecting certain products or suppliers and arriving at terms without open competition—would not be easily adaptable to Medicare, given the program's size and need to ensure access for providers and beneficiaries. How other federal agencies have exercised their leverage may offer more applicable lessons.

#### BACKGROUND

The traditional Medicare program does not have a comprehensive outpatient prescription drug benefit, but under part B (which covers physician and other outpatient services), it covers roughly 450 pharmaceutical products and biologicals.<sup>7</sup> In

<sup>5</sup>The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (P.L. 106-554, Appendix F).

<sup>6</sup>*Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Costs* (GAO-01-1118, Sept. 21, 2001.)

<sup>7</sup>For the remainder of this statement, we will refer to "drugs and biologicals" as "drugs."

1999, spending for Medicare part B-covered prescription drugs totaled almost \$4 billion.<sup>8</sup>

*Small Number of Products Accounts for Largest Shares of Program Spending and Claims Volume*

A small number of products accounts for the majority of Medicare spending and billing volume for part B drugs. In 1999, 35 drugs accounted for 82 percent of Medicare spending and 95 percent of the claims volume for these products.<sup>9</sup> The 35 products included, among others, injectible drugs to treat cancer, inhalation therapy drugs, and oral immunosuppressive drugs (such as those used to treat organ transplant patients).

The physician-billed drugs accounted for the largest share of program spending, while pharmacy supplier-billed drugs constituted the largest share of the billing volume. Three specialties—hematology oncology, medical oncology, and urology—submitted claims for 80 percent of total physician billings for part B drugs. Two inhalation therapy drugs accounted for 88 percent of the Medicare billing volume for pharmacy-supplied drugs administered in a patient's residence.<sup>10</sup>

*Medicare Payments for Drugs Are Based on Published AWP*

Medicare's payment for part B-covered drugs is based on the product's AWP, which is a price assigned by the product's manufacturer and may be neither "average" nor "wholesale." Instead, the AWP is often described as a "list price," "sticker price," or "suggested retail price."

The term AWP is not defined in law or regulation, so the manufacturer is free to set an AWP at any level, regardless of the actual price paid by purchasers. Manufacturers periodically report AWP to publishers of drug pricing data, such as the Medical Economics Company, Inc., which publishes the Red Book, and First Data Bank, which compiles the National Drug Data File. In paying claims, Medicare carriers use published AWP to determine Medicare's payment amount, which is 95 percent of AWP.<sup>11</sup> Thus, given the latitude manufacturers have in setting AWP, these payments may be unrelated to market prices that physicians and suppliers actually pay for the products.

*Drug Supply Chain Involves Multiple Parties and Arrangements That Influence the Net Price to the End Purchaser*

The actual price that providers pay for Medicare part B drugs is often not transparent. Physicians and suppliers may belong to group purchasing organizations (GPO) that pool the purchasing of multiple entities to negotiate prices with wholesalers or manufacturers. GPOs may negotiate different prices for different purchasers, such as physicians, suppliers, or hospitals. In addition, providers can purchase part B-covered drugs from general or specialty pharmaceutical wholesalers or can have direct purchase agreements with manufacturers.

Certain practices involving these various entities can result in prices paid at the time of sale that do not reflect the final net cost to the purchaser. Manufacturers or wholesalers may offer purchasers rebates based on the volume of products purchased not in a single sale but over a period of time. Manufacturers may also establish "chargeback" arrangements for end purchasers, which result in wholesalers' prices overstating what those purchasers pay. Under these arrangements, the purchaser negotiates a price with the manufacturer that is lower than the price the wholesaler charges for the product. The wholesaler provides the product to the purchaser for the lower negotiated price, and the manufacturer then pays the wholesaler the difference between the wholesale price and the negotiated price.

<sup>8</sup> Spending is defined as Medicare's total payment, of which Medicare's share is 80 percent and the beneficiaries' share is 20 percent.

<sup>9</sup> Our analysis excluded some high-volume and high-expenditure drugs because of inadequate pricing data. Volume for a drug is measured in terms of the number of units provided. Analyses exclude data on services supplied in Puerto Rico and the U.S. Virgin Islands and exclude payments made on behalf of Railroad Retirement Board beneficiaries.

<sup>10</sup> These two drugs are ipratropium bromide and albuterol (unit dose form).

<sup>11</sup> Technically, the payment equals 95 percent of AWP for the drugs grouped under each HCFA Common Procedure Coding System (HCPCS) code. Individual drugs are identified by the National Drug Code (NDC). NDCs are assigned by the Food and Drug Administration and are the universal product identifiers for drugs for human use. Each NDC specifies a chemical entity, manufacturer, dosage form, strength, and package size. For example, a single drug—marketed by one manufacturer in one form and strength but in three package sizes—would have three NDCs. Because one HCPCS code may have multiple NDCs, the carriers determine the Medicare payment by analyzing multiple NDCs' AWP. For multisource drugs, the payment allowance is 95 percent of the lower of (1) the median AWP of all generic forms of the drug or (2) the lowest brand name product's AWP.

MEDICARE'S PAYMENT FOR PART B-COVERED DRUGS IS SIGNIFICANTLY HIGHER THAN  
PRICES WIDELY AVAILABLE TO PROVIDERS

For the part B-covered drugs accounting for the bulk of Medicare spending and claims, Medicare payments in 2001 were almost always considerably higher than wholesalers' prices that were widely available to physicians and suppliers. This was true regardless of whether the drugs had competing products or were available from a single manufacturer. Physicians who billed Medicare for relatively small quantities of these drugs also obtained similar prices.

*Wide Disparities Exist Between Drug Acquisition Costs and Medicare Payments*

Our study shows that there can be wide disparities between a drug's estimated acquisition cost and Medicare's payment for that drug. Physician-billed drugs account for the bulk of Medicare spending on part B drugs. Of those billed by physicians, drugs used to treat cancer accounted for most of Medicare's expenditures. Specifically:

- Widely available discounts for 17 of the physician-billed drugs we examined averaged between 13 percent and 34 percent less than AWP.
- For two other physician-billed drugs, Dolasetron mesylate and Leucovorin calcium, average discounts were considerably larger—65 percent and 86 percent less than AWP.

The discounts on physician-billed drugs, based on wholesaler and GPO catalogue prices, are notably lower than Medicare's payment, which reflects a discount of 5 percent below AWP. The discounts indicate that Medicare's payments for these drugs were at least \$532 million higher than providers' acquisition costs in 2000. Further, the discounts we report may only be the starting point for additional discounts provided to certain purchasers, as chargebacks, rebates, and other discounts may drive down the final sale price.

Concerns have been expressed that small providers either could not or do not obtain such favorable prices. Therefore, we surveyed a sample of physicians who billed Medicare for low volumes of chemotherapy drugs to see if they were able to obtain similar discounts.<sup>12</sup> All of the low-volume purchasers who responded to our survey reported obtaining similar or better discounts than the widely available prices we had documented. More than one-third of these physicians reported belonging to GPOs and obtained the GPOs' substantial discounts, while others said they had contracts with manufacturers and wholesalers.

As with physician-billed drugs, Medicare's payments for pharmacy supplier-billed drugs generally far exceeded the prices available to these suppliers. For the drugs we examined, Medicare's payments were at least \$483 million more than what the suppliers paid in 2000. Further, the discounts we report were largest for products that could be obtained from more than one source. Inhalation therapy drugs administered through DME and oral immunosuppressive drugs represent most of the high-expenditure, high-volume drugs billed to Medicare by suppliers. Specifically:

- Two drugs, albuterol and ipratropium bromide, used with DME for respiratory conditions, account for most of the pharmacy-supplied drugs paid for by Medicare. In 2001, they were available to pharmacy suppliers at prices that averaged, respectively, 85 percent and 78 percent less than AWP.
- Other high-volume DME-administered drugs had prices averaging 69 percent and 72 percent less than AWP. These findings are consistent with prior studies of the prices of similar drugs.<sup>13</sup>
- Two of the four high-volume oral immunosuppressives were available from wholesalers with average discounts of 14 percent and 77 percent. Wholesale price information on the other two was not available, but retail prices from online pharmacies were as much as 13 percent and 8 percent below AWP.

*Policies to Pay for Related Delivery and Administration Services Vary by Provider*

Medicare payment policies for administering or delivering a drug vary, depending on who provides the drug to the patient. Physicians are compensated directly for drug administration through the physician fee schedule. Pharmacy suppliers are compensated for dispensing inhalation therapy drugs used with a nebulizer, which make up the majority of their part B drug claims. No explicit payments are made to pharmacy suppliers for dispensing other drugs, but they may receive payments for equipment and supplies associated with DME-administered drugs. Both physi-

<sup>12</sup> We conducted a telephone survey of a sample of physicians who billed Medicare for a low-volume of cancer treatment drugs in 1999. For more detail, see GAO-01-1118.

<sup>13</sup> Medicare Reimbursement of Albuterol (HHS OIG, OEI-03-00-00311, June 2000) and Medicare Reimbursement of Prescription Drugs (HHS OIG, OEI-03-00-00310, Jan. 2001).

cians and pharmacy suppliers contend that the excess in Medicare's payments for part B-covered drugs compensates for related service costs inadequately reimbursed or not explicitly covered at all.

In prior work on the Medicare physician fee schedule, we concluded that the agency's basic method of computing practice expense payments to physicians was sound.<sup>14</sup> The implementation of this fee schedule, however, has been controversial. The Congress required that payments be budget neutral relative to prior spending. Medicare's physician payments were, in the aggregate, seemingly adequate, as most physicians were participating in Medicare and accepting the program's fees as payment in full. Because of the budget neutrality requirement, if one specialty's fees increased on average, some others would have to decline. Such redistributions have occurred and some are significant.

Oncologists, who represent the majority of physicians billing for drugs, argue that Medicare's payments for administering chemotherapy are inappropriately low and that the excess Medicare drug payments are needed to offset their losses. Yet oncology is one of the specialties to gain under the resource-based physician fee schedule. In our separate study on physicians' practice expenses under Medicare's fee schedule, we will show that payments to oncologists were 8 percent higher than they would have been if the prior charge-based payment method had been maintained; the study will also show that oncologists' payments relative to their estimated practice expenses, which include chemotherapy administration, were close to the average for all specialties.

While oncologists do not appear disadvantaged overall under the fee schedule, adjustments HCFA made to the basic method of computing payments reduced fees for some oncologists' services. In those adjustments, HCFA modified the basic method in computing payments for services delivered without direct physician involvement, like much of chemotherapy administration. The modifications were intended to correct for perceived low payments for these services. While they increased payments for some of these services, they lowered them for many others. Moreover, they increased payments on average for services involving physicians. Oncology payments were particularly affected, as services without physician involvement constitute about one-third of oncologists' Medicare-billed services, compared to about 5 percent of all physician-billed services. Because of the modifications to the basic method, oncology practice expense payments for nonphysician chemotherapy administration were on average 15 percent lower, while payments for physician-administered services were 1 percent higher, than if HCFA had used the basic method. Across all services, the modifications resulted in oncology practice expense payments that were 6 percent lower.<sup>15</sup> Using the basic method for all services would eliminate these reductions and add about \$31 million to oncology payments. Our study will recommend that CMS revert to the use of the basic methodology to determine practice expense payments for all services.

We will also recommend that CMS address a data adjustment it made that affects oncology payments under the new fee schedule. The agency reduced oncology's reported supply expenses to keep from paying twice for drugs that are reimbursed separately by Medicare. Oncologists acknowledge that the supply expense estimate needed to be reduced, but argue that the reduction was too large. We have recommended that the agency develop the appropriate data to more accurately estimate oncology supply expenses. Substituting a supply expense estimate based on a methodology developed by the American Society of Clinical Oncology would raise practice expense payments an additional \$20 million,<sup>16</sup> if done in conjunction with our recommendation to use the basic method to calculate payments for all services.

Oncologists have raised concerns about whether the data used to estimate their practice expenses constituted a representative sample of practices surveyed and whether these data reflect current practices in delivering services. How improvements in the data to estimate practice expenses may affect payment levels is uncertain. Payments are based on the differences in expenses of services of one specialty compared to those of others. Some of the data concerns raised by oncologists may apply to other specialties as well, so that additional and more current data may reveal that the relative cost of one service compared to others may have changed only

<sup>14</sup> Practice expenses constitute one of three components in Medicare's physician fee schedule. The other two are work and malpractice expenses. For the physician's average fee in 1999, practice expenses accounted for about 42 percent; work, about 55 percent; and malpractice, about 3 percent.

<sup>15</sup> The source for these figures is our analysis of 2001 practice expense fees, based on 1999 Medicare utilization.

<sup>16</sup> The source for these figures is our analysis of 2001 practice expense fees, based on 1999 Medicare utilization.

modestly. We are conducting a separate study to determine how CMS can improve and update the information used to estimate specialties' practice expenses.

Similar to the physicians who bill for part B drugs, pharmacy suppliers and their representatives contend that the margin on the Medicare drug payment is needed to compensate them for costs not covered by Medicare—that is, the clinical, administrative, and other labor costs associated with delivering the drug. These include costs for billing and collection; facility and employee accreditation; licensing and certifications; and providing printed patient education materials. Medicare pays a dispensing fee of \$5.00 for inhalation therapy drugs used with a nebulizer, which are the vast majority of the pharmacy-supplied drugs. This fee was instituted in 1994. It is higher than dispensing fees paid by pharmacy benefit managers, which average around \$2.00, and is comparable to many state Medicaid programs, which range from \$2.00 to over \$6.00. For other pharmacy-supplied drugs, Medicare makes no explicit payment for dispensing the drug.

Besides the profits on the DME-related drugs, pharmacy suppliers may receive additional compensation through the payment for DME and related supplies. Our prior work suggests that, for two reasons, Medicare DME and supply payments may exceed market prices.<sup>17</sup> First, because of an imprecise coding system, Medicare carriers cannot determine from the DME claims they process which specific products the program is paying for. Medicare pays one fee for all products classified under a single billing code, regardless of whether their market prices are greatly below or above that fee.<sup>18</sup> Second, DME fees are often out of line with current market prices. Until recently, DME fees had generally been adjusted only for inflation because the process required to change the fees was lengthy and cumbersome. As a result, payment levels may not reflect changes in technology and other factors that could significantly change market prices.

#### OTHER PURCHASERS' PRACTICES ARE INSTRUCTIVE FOR REFORMING MEDICARE'S METHOD OF PAYING FOR PART B-COVERED DRUGS

Private insurers and federal agencies, such as VA, employ different approaches in paying for or purchasing drugs that may provide useful lessons for Medicare. In general, these payers make use of the leverage of their volume and competition to secure better prices. The federal purchasers, furthermore, use that leverage to secure verifiable data on actual market transactions to establish their price schedules. Private payers can negotiate with some suppliers to the exclusion of others and arrive at terms without clear criteria or a transparent process. This practice would not be easily adaptable to Medicare, given the program's size and need to ensure access for providers and beneficiaries. How other federal agencies have exercised their leverage may be more instructive and readily adaptable for Medicare.

VA and certain other government purchasers buy drugs based on actual prices paid by private purchasers—specifically, on the prices that drug manufacturers charge their “most-favored” private customers.<sup>19</sup> In exchange for being able to sell their drugs to state Medicaid programs, manufacturers agree to offer VA and other government purchasers drugs at favorable prices, known as Federal Supply Schedule (FSS) prices. So that VA can determine the most-favored customer price, manufacturers provide information on price discounts and rebates offered to domestic customers and the terms and conditions involved, such as length of contract periods and ordering and delivery practices.<sup>20</sup> (Manufacturers must also be willing to supply similar information to CMS to support the data on the average manufacturer's price, known as AMP, and best price they report for computing any rebates required by the Medicaid program.)

VA has been successful in using competitive bidding to obtain even more favorable prices for certain drugs. Through these competitive bids, VA has obtained national contracts for selected drugs at prices that are even lower than FSS prices. These

<sup>17</sup> See *Medicare: Need to Overhaul Costly Payment System for Medical Equipment and Supplies* (GAO/HEHS-98-102, May 12, 1998).

<sup>18</sup> The equipment and supply payment is determined from a DME fee schedule, whose rates are based on a state-specific fee schedule and subject to national minimum and maximum payment limits. Fees are based on average historical supplier charges that are adjusted for inflation over time.

<sup>19</sup> Under federal procurement regulations, the government seeks to obtain the price is intended to equal or better the price that the manufacturer offers its most-favored nonfederal customer under comparable terms and conditions.

<sup>20</sup> Because the terms and conditions of commercial sales vary, there may be legitimate reasons why the government does not always obtain the most-favored customer price. Hence, under the regulations, VA may accept a higher price if it determines that (1) the price offered to the government is fair and reasonable and (2) awarding the contract is otherwise in the best interest of the government.

contracts seek to concentrate the agency's purchase on one drug within therapeutically equivalent categories for the agency's national formulary. In 2000, VA contract prices averaged 33 percent lower than corresponding FSS prices.

Medicare's use of competition has been restricted to several limited-scale demonstration projects authorized by the Balanced Budget Act of 1997. In one of these demonstrations under way in San Antonio, Texas, suppliers bid to provide nebulizer drugs, such as albuterol, to Medicare beneficiaries. While Medicare normally allows any qualified provider to participate in the program, under the demonstration only 11 bidders for nebulizer drugs were selected to participate. In exchange for restricting their choice of providers to the 11 selected, beneficiaries are not liable for any differences between what suppliers charge and what Medicare allows. Preliminary CMS information on the San Antonio competitive bidding demonstration suggests no reported problems with access and a savings of about 26 percent realized for the inhalation drugs.

#### CONCLUDING OBSERVATIONS

Our study on Medicare payments for part B drugs shows that Medicare pays providers much more for these drugs than necessary, given what the providers likely paid to purchase these drugs from manufacturers, wholesalers, or other suppliers. Unlike the market-based fees paid by VA and other federal agencies, Medicare's fees are based on AWP, which is a manufacturer-reported price that is not based on actual transactions between seller and purchaser. Physicians contend that the profits they receive from Medicare's payments for part B drugs are needed to compensate for inappropriately low Medicare fees for most drug administration services. Similarly, the case argued by some pharmacy suppliers for Medicare's high drug payments is that not all of their costs of providing the drugs are covered.

In our view, it should be a principle of Medicare payment policy to pay for each service appropriately and not to rely on overpayments for some services to offset inadequate payments for complementary services. If Medicare were to follow this principle and lessons from other payers in setting fees for part B drugs, it would use information on actual market prices net of rebates and discounts—similar to information currently available to VA and CMS—to establish Medicare payments. It could also determine market-based fees, where appropriate, through a competitive bidding process. Medicare would pay for administration and delivery of these drugs separately, as it does currently for drugs supplied by physicians and for inhalation therapy drugs. As the way drugs are supplied and administered varies, different methods of determining payments would be necessary. Paying for these services explicitly would enable Medicare to eliminate implicit payments that may have been made through excessive payments for DME and the drugs associated with the DME payment. In our report, we make recommendations reflecting these lessons to revise the program's payment methods.

Messrs. Chairmen, this concludes my statement. I would be happy to answer any questions that you or Subcommittee Members may have.

#### CONTACT AND ACKNOWLEDGMENTS

For more information regarding this testimony, please contact me at (202) 512-7114 or Laura Dummit at (202) 512-7119. Other contributors to this statement include Carol Carter, Iola D'Souza, Hannah Fein, Kathryn Linehan, and James Matthews.

Mr. GREENWOOD. Thank you, Mr. Scanlon, for your testimony.

And I recognize Mr. Grob, the Deputy Inspector General for Health and Human Services, for your testimony, sir.

#### TESTIMONY OF GEORGE F. GROB

Mr. GROB. Thank you, Mr. Chairman, for the opportunity to testify here today. Everyone said Medicare pays too much, and listening to all the opening statements, I'm not sure that I have a whole lot to add to the knowledge that has already been presented.

Mr. GREENWOOD. I'm sure you have more credibility than we do.

Mr. GROB. What I'll try to do, perhaps, is to add some additional pieces of information that may help. First of all, with regard to the amount that we pay too much, the number that is being bandied around is about a billion dollars, and I think that is a fair bottom

line. Here is the reason. Our studies have shown, using the catalogs available that we've been able to find for 24 drugs, which represent about \$3.7 out of the \$5 billion in the year 2000 that Medicare authorized for the payment of these drugs, that we saw a loss of about \$880 some-odd million. Of course, if we had looked at all the drugs, that would have been higher and perhaps pressing a billion dollars. So that is a fair benchmark for people to have in their minds.

But we have to remember that these are catalog prices. These are the numbers that are sort of out there. So when the drugs are actually paid for, it is very likely that the prices are even lower than that. We ourselves did not obtain those lower prices. Ours are the more conservative, just catalog price.

Now, we've also looked at the Federal Supply Schedule which is negotiated by the Veterans Administration, and there, of course, we found a \$1.9 billion difference in the spread. Now, many people would say that that's unfair because of the special position that the Veterans Administration is in; that you really can't say, well, Medicare ought to be able to get drugs at those prices. That may be true, but here are some things to think about.

First of all, we assume that the drug companies are making a profit on those drugs, so that that represents a price that they are willing to offer to at least some large buyers. And we're not at all certain, since we ourselves did not look at the actual invoices, of what the spreads are that physicians and others—large suppliers—are actually obtaining on their drugs. Perhaps it's an outer limit, but I think it's fair to say that the actual loss to Medicare is probably in the vicinity of \$1 to \$2 billion, as best we can tell.

Another point that I would make is that we have reviewed these drug prices intensely, starting in the mid-1980's because, of the effects to Medicaid program as well, but we have been looking particularly hard since 1997. And over the last 4 years, we have never found it to be any way other than what has been described at this hearing. Every study that we do finds these same results. But near the end of my testimony, I'm going to reflect that the gap is widening, and the loss is increasing.

We've talked about the system being flawed, and I think most people describe it well. And I do take to heart the admonition not to get to the motives of people. But I just would like to give two insights about this.

If you were to sit down in an office with an individual, a representative of the drug company here and perhaps a physician here, and say, "Listen, I will sell you the drug for \$100, but I will tell Medicare that I sell it for \$200, you will have \$100, and I will have \$100. It's not a bad deal." Someone then might comment that a kind of deal has been made, perhaps games are being played to achieve a higher market share by that drug company, presenting its drug in that way. But that would still be true, even if the meeting doesn't occur in the room. This is not too hard to understand. Simply posting of these numbers on a public list is enough to achieve the same effect. So we have to be wary of the effect even if in the studies that I have done we have not reached the motives of the individuals.

There's also something here that I call "upside-down economics." If I were to ask an undergraduate economic student the following question: "Which company would likely achieve the greatest market share? Is it the one with the highest average wholesale price or the one with the lowest?" And the student were to say: "It's the one with the highest." The professors would say; "That is incorrect. Obviously the company whose wholesale price is the lowest would be the one that would expect to sell more of their product." That is the answer the professor would have to give, of course, unless you're talking about Medicare's payment for prescription drugs—in which the whole theory simply reverses.

The physician community has raised its concerns here, and we certainly take that to heart. We fully support a fair reimbursement under the Medicare program.

Perhaps another insight will help here. What I believe is wrong with the current system is that it's behaving this way. If an individual felt that his mortgage payments were too high, he might want to go to the bank and say: "Since you're charging me so much there, could you reduce my automobile payment?" Well, that's not a good way to do banking, but it might not be an unreasonable question.

The problem with the Medicare program is that in an analogous situation, the automobile dealer and the automobile purchaser are telling the bank how much they will pay for the car payment as opposed to the Medicare program, the Secretary, the Department and the Congress deciding what that amount is. And I believe that that's fundamentally what's wrong, even if we do have some compassionate concern for the dollars that the medical profession needs to carry out what it does.

In any event, whatever system that we do use should not be based on a number that is misnamed, misleading, and make believe.

There are a lot of options to handle this problem, and we've listed them extensively in the testimony that we've provided. It's too detailed to discuss here in my short version of my testimony, but we have made ourselves available and will continue to answer as many technical questions as we possibly can.

Let me end now by making one other remark. I think that we have all felt strongly that we have a problem here that needs to be fixed. What I would like to emphasize is that we fix it now. The first really detailed study that we did of the current phenomenon was in 1997 based on 1996 dollars, and here were the facts then: Medicare's authorization for drugs was \$2.3 billion that year. We looked at \$1.5 billion and found \$447 million that was probably wasteful. Four years later, looking at the data from the year 2000, the amount that Medicare authorized for drugs had more than doubled to \$5 billion. We looked at \$3.7 billion, and even the conservative estimate, the catalog estimate, we found was double what we found in terms of waste—possible waste for the government was \$900 million and possibly as much as \$1.9 billion. So every day, every month, every period that we don't solve the problem, the problem gets bigger, and the Medicare expenditures rise. Thank you.

[The prepared statement of George F. Grob follows:]

PREPARED STATEMENT OF GEORGE F. GROB, DEPUTY INSPECTOR GENERAL FOR  
EVALUATION AND INSPECTIONS, OFFICE OF INSPECTOR GENERAL, HHS

Good morning Mr. Chairman. I am George Grob, Deputy Inspector General for Evaluation and Inspections, Department of Health and Human Services. I am here today to discuss Medicare payments for prescription drugs.

Medicare pays too much for prescription drugs—more than most other payers. The method it uses to determine the amount to be paid is flawed. In fact, it makes no sense at all. It allows the price to be set arbitrarily by drug manufacturers, not the marketplace. Their published wholesale prices for many drugs are far above what suppliers and physicians actually pay for them. This allows physicians, for example, to make substantial profits from the drugs they administer during the course of treatment in their offices. For the year 2000 we found that Medicare's authorized payments for 24 leading drugs were \$887 million more than actual wholesale prices available to physicians and suppliers and \$1.9 billion more than prices available through the Federal Supply Schedule. Until the system is changed, Medicare and its beneficiaries will continue to pay excessive amounts for prescription drugs; and the amount of excessive payments will increase every year.

MEDICARE COVERAGE AND PAYMENTS FOR PRESCRIPTION DRUGS

Medicare's coverage of outpatient drugs is limited primarily to drugs used in dialysis, organ transplantation, and cancer treatment. Medicare also covers certain vaccines and drugs used with durable medical equipment such as infusion pumps and nebulizers. However, Medicare's total payments for prescription drugs have risen steadily over the past decade. In 1992, Medicare paid about \$700 million for prescription drugs; by 2000, it paid \$5 billion. Between 1999 and 2000 alone, payments increased by \$1 billion. This rapid growth illustrates the necessity of ensuring that Medicare pays reasonable prices for the drugs it covers.

Physicians and suppliers purchase these drugs, administer or provide them to Medicare beneficiaries, and then submit a bill to Medicare for reimbursement. In general, Medicare reimburses physicians and suppliers for 95 percent of the average wholesale price (AWP) published by the drug manufacturers. Of this amount, Medicare beneficiaries are responsible for a 20 percent coinsurance payment.

EXCESSIVE PAYMENTS

Over the past 4 years, the Office of Inspector General has produced a number of reports, all of which have reached the conclusion that Medicare and its beneficiaries pay too much for prescription drugs. Although it might be sufficient for me to quote only from our most recent studies, I would like to summarize all of our work here, because it demonstrates the consistency of our findings and the relentless growth of the problem.

A table summarizing the results of our reports is provided on the next page, followed by a more detailed description.

Summary of OIG Medicare Prescription Drug Reports

Year of Report	1997	1998	2000	2000	2000	2001	2001
Drugs Reviewed ...	22 drugs	34 drugs	5 ESRD drugs	Albuterol	24 drugs	Albuterol	24 drugs
Year Reviewed .....	1996	1997	1998	1999	1999	2000	2000
Medicare Expenditures for Reviewed Drugs ...	\$1.5 billion	\$2.1 billion	\$379 million	\$246 million	\$3.1 billion	\$296 million	\$3.7 billion
Excessive Payments Based On:							
VA .....		\$1 billion	\$162 million	\$209 million	\$1.6 billion	\$264 million	\$1.9 billion
Catalogs .....	\$447 million				\$761 million	\$245 million	\$887 million
Medicaid .....			\$42 million	\$120 million	\$425 million		
Beneficiary Share of Excessive Payments .....	\$89 million	\$200 million	\$32 million \$8 million	\$42 million \$24 million	\$320 million \$152 million \$85 million	\$53 million \$49 million	\$380 million \$177 million

*Drugs in general*

In December 1997, we released a report which compared Medicare payments for 22 drugs to actual wholesale prices available to the physician and supplier communities. These 22 drugs accounted for \$1.5 billion of the \$2.3 billion in Medicare payments for prescription drugs in 1996. The wholesale prices were computed using catalogs from drug wholesalers and group purchasing organizations which sell drugs to physicians and suppliers.

The report found that Medicare allowances for the 22 drugs exceeded wholesale prices by \$447 million in 1996. Medicare paid more than the available wholesale price for all 22 drugs under review. For more than one-third of the drugs, Medicare reimbursement amounts were more than double the wholesale prices available to the physician and supplier community.

We followed up this report in November of 1998 by comparing Medicare allowances for prescription drugs to prices available to the Department of Veterans Affairs (VA) and several other Federal agencies through the Federal Supply Schedule (FSS). (The supply schedule provides agencies like the VA with a simple process for purchasing commonly-used products in various quantities while still obtaining the discounts associated with volume buying. Using competitive procedures, contracts are awarded to companies to provide services and supplies at the FSS prices over a given period of time.) This report included 34 drugs which accounted for \$2.1 billion of the \$2.8 billion in Medicare spending for prescription drugs in 1997.

We found that Medicare and its beneficiaries would have saved \$1 billion in 1998 if the allowed amounts for the 34 drugs were equal to prices obtained through the FSS. The potential savings for just one drug, leuprolide acetate, accounted for over \$275 million. Medicare paid more than double the VA for 14 of the drugs. Overall, it paid between 15 percent and 1600 percent more than the VA for each of the 34 drugs. The biggest difference was for the drug leucovorin calcium, with a VA price of \$1.18 and a Medicare price over \$20.

In January of this year, we released another report comparing Medicare reimbursement to prices available to the physician/supplier community, the Department of Veterans Affairs, and Medicaid. This time, we studied the prices for 24 drugs which represented \$3.1 billion of the \$3.9 billion in Medicare drug expenditures in 1999.

We found that Medicare and its beneficiaries would have saved \$1.6 billion for these 24 drugs by paying the VA's Federal Supply Schedule price. For half of the drugs, Medicare paid more than double the VA price. The savings would have been \$761 million a year by paying the actual wholesale prices available to physicians and suppliers. For every drug in our review, Medicare paid more than the wholesale price available to physicians and suppliers and the VA Federal Supply Schedule price. For example, Medicare reimburses \$43 for 10 mg of the drug doxorubicin, more than four times the wholesale price of \$10. The VA pays even less, with a Federal Supply Schedule price of \$6.29. We also found that Medicare would have saved over \$425 million or almost 15 percent a year for the 24 drugs by obtaining rebates similar to the Medicaid program.

We have recently updated the findings of this report with more current drug pricing information. We found that Medicare would have saved \$1.9 billion of the \$3.7 billion it spent for 24 drugs in 2000 if the drugs were reimbursed at prices available to the VA. Over \$380 million of this savings would directly impact Medicare beneficiaries in the form of reduced coinsurance payments. In some cases, the VA price for a drug was less than the amount a Medicare beneficiary would pay in coinsurance. More conservatively, Medicare and its beneficiaries would save \$887 million a year by paying the actual wholesale prices available to physicians and suppliers for these 24 drugs. Beneficiaries would pay over \$175 million less in coinsurance if Medicare paid for these drugs based on catalog prices. The potential savings to both Medicare and its beneficiaries is probably higher, assuming data for all Medicare drugs is similar to that for the 24 we analyzed.

*Nebulizer and End Stage Renal Disease (ESRD) Drugs*

In addition to our reports summarizing a number of drugs, we have also produced targeted reports on specific nebulizer and end stage renal disease (ESRD) drugs that Medicare covers.

In June 2000, we released a report which looked at Medicare's reimbursement of albuterol, a drug used with a nebulizer to treat asthma, emphysema, and other respiratory problems. Albuterol is one of the top drugs covered by Medicare, with more than \$250 million per year in Medicare allowances. This report updated the findings of several of our prior albuterol studies, all of which noted that Medicare's reimbursement amount exceeded prices available through other sources.

We found that Medicare paid nearly double the Medicaid payment amount and almost seven times what the VA pays for one milligram of albuterol. Furthermore, nearly every pharmacy we contacted sold generic albuterol at prices less than Medicare paid for it. According to our survey results, consumers could go to popular drug stores across the country and buy a monthly supply of albuterol for around \$95. For the same monthly supply, Medicare and its beneficiaries would pay a total of \$118, with Medicare paying \$94 and the beneficiary paying the remaining \$24. The VA's entire monthly payment of \$17.50 for albuterol is less than just the beneficiary's \$24 coinsurance payment under Medicare. We calculated that Medicare could save between \$47 million and \$209 million per year by setting prices for albuterol equal to those available through these other sources.

Once again, we have recently updated this report with new pricing data. Preliminary findings show that VA prices for albuterol have decreased since last year. The VA price for albuterol has fallen by more than 50 percent over the last 3 years, from \$0.11 per mg in 1998 to \$0.05 per mg in 2001. During the same time period, Medicare's reimbursement amount (based on reported average wholesale prices) has remained constant at \$0.47 per mg.

In 2000, published wholesale acquisition costs for albuterol ranged from \$0.09 to \$0.18 per mg. These wholesale acquisition costs were provided by manufacturers to drug compendiums such as Red Book. The Medicare reimbursement rate of \$0.47 per mg was anywhere from three to five times the wholesale acquisition costs reported by manufacturers.

Recently, we have begun to look at who actually supplies albuterol to Medicare beneficiaries. We found that Medicare reimbursed more than 6,500 pharmaceutical suppliers for albuterol claims in 2000. However, less than 3 percent of these suppliers (184) accounted for approximately 80 percent of albuterol reimbursement. Each of these suppliers had over \$150,000 in paid Medicare claims for albuterol last year. Thirty-four of these suppliers were each responsible for more than \$1 million in Medicare reimbursement for albuterol in 2000, with five having between \$11 million and \$35 million in reimbursement. Thus, the vast majority of the albuterol supplied to Medicare beneficiaries was provided by suppliers that purchase and bill for a large quantity of the product. We believe that suppliers that purchase albuterol in such large quantities are likely to receive volume discounts similar to those provided to the VA and other large purchasers. Our work in this area is continuing.

Also in June 2000, we released a report comparing Medicare payments for ESRD drugs to those of the VA and Medicaid. We focused this inspection on five drugs used by renal dialysis facilities to help treat renal failure. These five drugs accounted for \$379 million in total charges to Medicare in 1998.

We found that Medicare paid between 37 percent and 56 percent more than the VA for these drugs. Medicare would have saved up to \$162 million in 1998 if they paid the same amount as the VA for the five drugs. Furthermore, Medicare paid between 5 percent and 38 percent more than Medicaid. Medicare would have saved as much as \$42 million in 1998 by using Medicaid reimbursement amounts.

#### FLAWED PAYMENT METHOD

Our reports have shown time after time that Medicare pays too much for drugs. Why does Medicare pay so much? We believe that it is because Medicare's payment methodology is fundamentally flawed. By statutory requirement, Medicare's payment for a drug is equal to 95 percent of the drug's average wholesale price (AWP). However, the AWP's which Medicare uses are not really wholesale prices.

For the most part, AWP's are reported by manufacturers to companies that compile drug pricing data, such as First DataBank and Medical Economics which publishes the Red Book. As our reports have indicated, the published AWP's that Medicare uses to establish drug prices bear little or no resemblance to actual wholesale prices available to physicians, suppliers, and large government purchasers.

Aside from the obvious problem of inflated AWP's resulting in inappropriate Medicare payments, the use of AWP also has other potential adverse side-effects. For instance, because physicians and suppliers get to keep the difference between the actual price they pay for the drug and 95 percent of its AWP, this "spread" can serve as an inducement for suppliers or physicians to use one brand of drug product over another. Thus, publishing an artificially high AWP can be used as a marketing device to increase a drug company's market share. Such a tactic would increase the profit of the suppliers or physicians who purchase the drug because, while not paying the artificially inflated AWP amount, they can bill Medicare for it and get paid at that inflated amount. While the published AWP does not increase the amount the manufacturer receives for each unit of the drug product, it may induce an increase in market share because of the higher profits made by physicians and sup-

pliers. This in turn increases the profits of the drug company. All of this occurs at the expense of the Medicare program and its beneficiaries.

For the drug albuterol, the spread is so large and Medicare reimbursement so lucrative that mail-order pharmacies have been tempted to capitalize on the difference by making illegal kickback payments to durable medical equipment suppliers for patient referrals. A civil settlement totaling \$10 million has been reached with one pharmacy that succumbed to this temptation.

#### PHYSICIANS' CONCERNS

Some physician groups have raised concerns about Medicare's attempts to lower reimbursement for prescription drugs. For example, some oncologists have stated that Medicare does not adequately reimburse physicians for the practice costs associated with providing treatment to cancer patients. These physician groups say that overpayments for prescription drugs simply make up for inadequate payments for their practice costs.

We agree that physicians need to be properly reimbursed for patient care. However, we do not believe that the payment of artificially inflated drug prices is an appropriate mechanism to compensate them. We do not think that the decision as to how much Medicare pays for physicians' practice costs should be made by them or by drug manufacturers. The Medicare program or the Congress should have responsibility for this calculation. We certainly do not believe that the basis for their compensation and medical practice expenses should be artificially inflated, misleading, and mis-named average wholesale prices.

The Medicare program already has a procedure for determining and the amount of paying physicians for their practice costs. If the current calculations are incorrect, they should be modified. Physicians deserve fair reimbursement for their valuable services. There is no reason to resort to a make-believe process to accomplish this.

#### OPTIONS FOR REFORMING THE PAYMENT SYSTEM

There are a number of options for revising Medicare's drug reimbursement methodology. We recognize that there may not be one perfect solution to solving all of Medicare's drug pricing issues. However, we believe these options provide reference points for considering how to reform the Medicare drug payment system.

A few general remarks are in order before discussing specific options. First, some of the options offer a way to calculate a base amount for Medicare reimbursement. These include using the Federal Supply Schedule, the average manufacturer's price, or the AWP, for example. For each such option, additional sub-options are possible. One would be to set Medicare prices at a fixed percentage above or below the base. For example, Medicare currently has its payment rate set at 95 percent of AWP. That percentage could be dropped. Alternatively, if the Federal Supply Schedule were used as a base, then Medicare's payment could be set at, say, 105 or 110 percent of this number.

Second, the options are not necessarily exclusive of one another. In the Medicaid program, most States set payment rates at a percentage below AWP, but they also get rebates from manufacturers. The same could be done for Medicare. Another example might be basing Medicare payment rates on average manufacturer prices (AMP) (used for calculating rebates in the Medicaid program), but making upward or downward adjustments on the basis of surveys of amounts paid by of large institutional health care providers such as hospitals or managed care organizations.

Each option has its own advantages and disadvantages. Some things to consider when comparing them are: the cost of gathering data to set the base, the reliability of the data, the time needed to collect and analyze it; how easily it can be gamed or misrepresented.

Logistical considerations are important too, such as: who will collect and analyze data, who will propose the Medicare payment rate, and how often this will be done; how will the underlying data be verified, by whom, and how often; what method will be used to periodically update the payment amounts, and how frequently will this be done.

Finally, some broader principles and concerns need to be addressed, such as: how proprietary data will be protected; the consequences of drug manufacturers, suppliers, wholesalers, and medical care providers not providing the needed data or misrepresenting it; ways to minimize the burden of public reporting associated with data collection; the need for, nature of, and length of a transitional phase in introducing the new payment method; and whether any adjustment is needed in the practice cost component of Medicare's physician payment rate.

Keeping these factors in mind, the following options may be considered for reforming Medicare's drug payment method:

**1. Authorize a commission to set payment rates.** A commission could be established similar to MEDPAC, which recommends rate increases for Medicare hospital and physician payments and analyzes prices and economic trends. Such a commission could recommend a periodic update of Medicare prices based on a market basket of drugs, including any new drugs. It would be granted authority to require manufacturers to provide them with drug wholesale prices, but would not disclose any of the proprietary data collected from manufacturers.

**2. Calculate national estimated acquisition costs based upon the average manufacturer prices (AMP) reported to the Medicaid program.** The Centers for Medicare & Medicaid Services (CMS) could calculate reimbursement rates using AMP and send these rates out to the Medicare carriers. Average manufacturer prices are currently reported to CMS under the drug rebate program, and they more accurately reflect the prices paid by drug wholesalers to manufacturers. If this option were used, it would eliminate the need to go to the manufacturers for more pricing information. This option would require legislation to allow Medicare access to AMP data. Prior to this option being implemented, it would be useful to clarify or refine certain definitions. We also believe an initial, intensive effort should be made to audit AMP data reported by manufacturers to validate its accuracy. We estimate that in the year 2000 Medicare and its beneficiaries would have saved \$1.4 billion of the \$3.7 billion spent on just 24 drugs if reimbursement for the drugs had been based on AMP.

**3. Collect more accurate average wholesale prices from drug pricing catalogs or other sources.** This option would entail requiring manufacturers or wholesalers to provide their pricing information or catalogues to an appropriate commission or federal agency. Protection of the confidentiality of proprietary data could be guaranteed in the authorizing statute.

**4. Increase the discounting of the published AWP.** If this option were used, a provision would be needed to prevent manufacturers from just raising AWP by an amount greater than the newly discounted rate.

**5. Base payment on physician/supplier acquisition costs.** This option would require obtaining invoices of actual payments made. Payment could not be based solely on the listed invoice price as that price often gets discounted by rebates and volume discounts. Net cost would need to be obtained and this might be difficult because many of the manufacturers rebates are not calculated until the end of the year. Additionally, since Medicare would be reimbursing drugs based on cost there would be little incentive to get the best price.

**6. Establish manufacturers' rebates similar to those used in the Medicaid program.** A Medicare rebate program could be modeled on Medicaid's program. However, if a Medicare rebate program were used in conjunction with, instead of as a replacement for the current AWP system, then the rebates should be based on AWP rather than the AMP used by Medicaid. This would minimize manufacturers' incentives to inflate AWP because rebates would increase as AWP increased.

**7. Create a fee schedule for covered drugs based on the Federal Supply Schedule negotiated by the Department of Veterans Affairs.** The payment amounts could be set at the Federal Supply Schedule price or that price plus a certain percentage.

**8. Use CMS's inherent reasonableness authority.** This authority allows CMS to reduce its payment rates if it can be shown that payment amounts are excessive. A recent study by the General Accounting Office (GAO), mandated by the Congress, found this authority to be appropriate, and it supported some recent studies performed by CMS in its proposed use of it. According to the law which mandate the GAO study, the inherent reasonableness authority may be used as soon as CMS promulgates regulations for it.

**9. Use competitive bidding.** The CMS currently has the authority to demonstrate the efficacy of competitive bidding for medical supplies. The demonstrations have already proven that inhalation drugs can be obtained at prices lower than 95 percent of AWP. A statutory amendment to make general use of this authority might be appropriate, at least for some categories of drugs, particularly those which are provided by a small number of suppliers or by mail-order firms.

#### CONCLUSION

There can be no doubt that Medicare pays too much for prescription drugs. This finding has been confirmed year after year. At the same time, Medicare payments overall, including excessive amounts, are increasing substantially. This adversely affects the Medicare trust fund and Medicare's beneficiaries, who are responsible for 20 percent of the bill. While no payment method will perfectly address all conceivable technical problems, many options are available that are superior to the current

payment method, with its misleading nomenclature and artificially inflated prices. Currently, Medicare payments are being set not by the Medicare program but by drug manufacturers and indirectly by health care providers. Until this problem is corrected Medicare and its beneficiaries will unnecessarily pay more and more each year.

I hope this testimony has been constructive in explaining the problem and offering some ideas for its solution.

Mr. GREENWOOD. I thank the gentleman and would note that even if we passed legislation that was signed into law tomorrow, it's probably going to take 6 to 9 months to begin to achieve the saving just because of the bureaucratic necessities.

The Chair recognizes Mr. Zachary Bentley, President of Ven-A-Care Inc., for your testimony, sir.

#### **TESTIMONY OF ZACHARY T. BENTLEY**

Mr. BENTLEY. Mr. Chairman, members of the subcommittee, good morning. I am Zachary T. Bentley. For the last 13 years, I've been an officer and a business manager of Ven-A-Care of the Florida Keys, a small pharmacy located in Key West, Florida. Early on, I was shocked to receive a payment from Medicare for the infusion cancer drug Leucovorin that exceeded our costs by approximately 1,000 percent.

Mr. GREENWOOD. Mr. Bentley, could you pull the microphone just a little closer, please?

Mr. BENTLEY. The tenfold profit on this drug being paid for by Medicare was so excessive that the beneficiary's 20 percent copayment actually exceeded the cost of the drug to Ven-A-Care.

I attempted to return the payment, only to learn that the Medicare carrier did not believe it had made a mistake. The prices used by Medicare, Medicaid and many private health insurers for setting drug reimbursements are the prices reported to those entities by drug manufacturers. We have discovered that some, not all, drug manufacturers report falsely inflated prices so that their customers will reap exorbitant windfall profits.

In 1991, Ven-A-Care was solicited to enter into a physician joint venture designed to split the proceeds of such excessive reimbursements with doctors in a position to prescribe expensive infusion drugs to AIDS patients. The venture was crafted by one of the country's largest health care companies, National Medical Care, then a subsidiary of W.R. Grace. We were promised by NMC that we would become wealthy if we cooperated. We refused because we believed that this proposal was nothing more than a kickback scheme, which would ultimately lead to overutilization of drugs and possibly patient harm.

National Medical Care then proceeded with the physician joint venture on its own and effectively ran Ven-A-Care out of business. Later when Ven-A-Care attempted to rebuild its business with a focus on oncology drug therapies, we encountered demands that we enter into a similar kickback arrangement with oncologists associated with yet another large national health care company. Again, we declined to participate. Instead, we redoubled our efforts to shine the light of day on these shadowy schemes.

We have worked diligently to educate those who administer Medicare and Medicaid programs about this serious problem, including personally briefing the previous HCFA Administrator. We

have assisted the HHS Office of Inspector General, the Department of Justice, and have prosecuted false claims actions that resulted in the government's nearly \$500 million recovery against National Medical Care and the more recent \$14 million Medicaid settlement with Bayer Pharmaceuticals Corporation. We also initiated the pending Texas Medicaid false claims action against inhalation drug manufacturers Warrick, Roxane and Dey Laboratories. Texas Attorney General John Cornyn has joined with us in that case.

Last year we were subpoenaed by your committee to provide our information relating to this drug pricing fraud. The information we provided reveals some troubling things. A fraud scheme costs the government billions of dollars each year and encompasses not only chemotherapy drugs, but drugs used for inhalation, biologicals, IV fluids, IV antibiotics, and now it is in the community retail marketplace.

Medicare and Medicaid patients are harmed when health care providers' decisions to prescribe and dispense drugs are based on profit rather than the best interest of the patient. The fraud adds to the spiralling Medicaid drug expenditures that have forced some States to curtail other needed public health services. Medicare patients are defrauded because their 20 percent copayment alone often exceeds 100 percent of the true cost of the drug.

Americans are being deprived of newer and safer drugs when manufacturers inflate price reports of newer drugs to encourage physicians to keep prescribing the older drugs. Government programs are deprived of the benefits of vigorous price competition when expensive drugs become subject to competition by generics, other patented drugs or other kinds of treatments. Prices drop in the marketplace, but prices reported to the government remain at the same level or in some instances actually rise. Those drug manufacturers making false price representations have effectively usurped the right and duty of Congress to determine Medicare drug payments and the right and duty of your State legislators and Congress to determine Medicaid drug payments. Our existing Medicare drug reimbursement system is broken only because some, not all, drug companies have chosen to falsely report inflated prices.

And finally, no expanded Medicare drug benefit can successfully be implemented unless drug companies are required to tell the truth about their prices.

Thank you very much. I'll be happy to answer any questions.

[The prepared statement of Zachary T. Bentley follows:]

PREPARED STATEMENT OF ZACHARY T. BENTLEY, PRESIDENT, VEN-A-CARE OF THE FLORIDA KEYS, INC.

Mr. Chairman and Members of the Subcommittees: Good morning. I am Zachary T. Bentley.

For the last thirteen years I have been an officer and the business manager of Ven-A-Care of the Florida Keys, a small pharmacy located in Key West, Florida. Early on, I was shocked to receive a payment from Medicare for the infusion cancer drug, Leucovorin, that exceeded our cost by approximately 1000%. The ten-fold profit on this drug, being paid for by Medicare (80%) and the beneficiary (20%), was so excessive that the beneficiary's co-payment actually exceeded the cost of the drug to Ven-A-Care. I thought the Florida Medicare carrier had made a mistake. I attempted to return the payment, only to learn that the Medicare program in fact assumed that the cost of Leucovorin was many times greater than the true price available to even a small company such as Ven-A-Care.

We communicated pricing information about Leucovorin and other drugs which we discovered had similar pricing and reimbursement disparities, to the Health Care Financing Administration and other federal and state agencies, in an effort to alert them to the problem. We learned that the prices used by Medicare, Medicaid, and many private health insurance programs for setting drug reimbursements were the prices reported to those entities by the drug companies. When the manufacturers report falsely inflated prices, providers reap exorbitant windfall profits. Those windfall profits serve the drug manufacturers as government-funded kickbacks to induce the providers to order their drugs.

I must emphasize, however, that not all pharmaceutical manufacturers engage in this nefarious scheme.

In 1991, Ven-A-Care was solicited to enter into a physician joint venture designed to split the proceeds of such excessive reimbursements with doctors in a position to prescribe expensive infusion drugs to AIDS patients. The venture was crafted by one of the country's largest healthcare companies, National Medical Care, then a subsidiary of WR Grace. We were promised by NMC that we would become wealthy if we shared drug revenues with the treating physicians, because they would order large quantities of pharmaceuticals that cost far less than the reported prices. We believed that this proposal was nothing more than a kickback scheme, which ultimately would lead to over-utilization of drugs and possibly to patient harm, and we elected to not participate. National Medical Care then proceeded with the physician venture on its own and effectively ran Ven-A-Care out of business.

Later, when Ven-A-Care attempted to rebuild its business with a focus on oncology drug therapies, we encountered demands that we enter into similar kickback arrangements with oncologists associated with yet another large national healthcare company. Again, we declined to participate. Instead, we redoubled our efforts to shine the light of day on these shadowy schemes.

We learned that almost every third-party payer, including Medicare, Medicaid, the Federal Employees Health Benefits Plan, and most private insurers, relied on the drug companies' representations of drug prices when setting the reimbursement amounts paid to providers. It became apparent to us that many drug manufacturers reported truthful prices, while others falsely inflated their price reports so that their targeted customers—oncologists, urologists, home care companies, ESRD providers, DME companies, and others—would be induced by the resulting windfall profits to order their drugs.

We have worked diligently to educate those who administer the Medicare and Medicaid programs about this serious problem, including personally briefing the previous HCFA Administrator. Ven-A-Care also has taken direct action to stop this major hemorrhage of tax dollars. We have assisted the HHS Office of Inspector General and the Department of Justice and have prosecuted False Claims actions that resulted in the government's nearly \$500,000,000 recovery against National Medical Care/Fresenius and the more recent \$14,000,000 Medicaid settlement with Bayer Pharmaceutical Corporation.

We also initiated the pending Texas Medicaid false claims action against Schering Plough's Warrick drug division, Boehringer Ingelheim's Roxane drug division, and Dey Laboratories. Each of those companies manufacture inhalation drugs used to treat severe respiratory ailments. Texas Attorney General John Cornyn has adopted our claims, and we are currently assisting him in that litigation. The Texas Medicaid Program has led the Nation in its efforts to secure accurate price reports from drug companies by requiring written certification of a range of prices.

Last year, pursuant to subpoena, we provided to the House Committee on Energy and Commerce our documents and other evidence relating to the inflation of price reports by certain drug companies. In preparing for my testimony today, I have again reviewed the information now in the Committee's possession. The Committee's commendable oversight and investigative efforts have alerted the Congress and the public to the following issues:

- 1.) The evidence reveals that the fraud scheme encompasses a wide range of drugs including chemotherapy, inhalants, biologicals, IV fluids, and, IV antibiotics. More recent reports reveal that the fraud is also directed at oral drugs reimbursed by Medicaid and which will be the focus of an expanded Medicare drug benefit.
- 2.) Falsely inflated drug price representations enrich certain health care businesses, including some drug companies, home care pharmacies, oncologists, and inhalation providers, while cheating Medicare beneficiaries of their current drug benefits. This shameful fraud levies a cruel tax on Medicare beneficiaries, whose 20% co-payment alone often exceeds 100% of the true, reasonable cost of the drug to health care providers.

- 3.) This fraud compromises the health and safety of Medicare and Medicaid patients. The excessive reimbursements are used as inducements to physicians and other health care providers in a position to cause the companies' drugs to be ordered. Oncologists and other providers are thus financially induced by certain drug manufacturers to prescribe such vital drugs as chemotherapies, not on the basis of what is best for the patient, but based on what is most profitable for the medical provider. Such kickback schemes impair independent medical judgment and interfere with the physician/patient relationship. A case in point involves the prostate cancer drug Lupron, manufactured by TAP Pharmaceuticals, a joint venture between Japan's Takeda Pharmaceutical Company and Abbott Labs. Recently announced criminal indictments of several urologists illustrates the seriousness of the problem.
- 4.) The price fraud costs Medicare and Medicaid billions of dollars each year in the form of excessive reimbursements and over-prescribing of medications.
- 5.) False, inflated drug price representations effectively deprive Medicare and Medicaid patients of access to medical care because:
  - a.) Seniors are overcharged in their co-payments and thus have less money available to purchase other needed drugs not covered by Medicare.
  - b.) Scarce health care program dollars are diverted to fund these overpayments and kickbacks that benefit practice specialties in a position to increase drug company sales. The Wall Street Journal reported last February 7 that "states say the drug-cost component of Medicaid is rising more than 20% annually," forcing states to cut funding for other services. Missouri budget director Brian Long told the Journal that Medicaid costs are responsible in part for his state's inability to fund increased costs for school transportation and special education. An Ohio budget official said "The rest of state government is dramatically impacted" by rising Medicaid drug costs. Similarly, scarce Medicare dollars are diverted and thus not available, therefore, to increase reimbursements to other practice specialties such as cardiology, surgery, and gynecology.
- 6.) Certain drug manufacturers and health care provider groups have actively misled Congress and the Medicare and Medicaid programs in an effort to conceal and perpetuate this fraud. Examples include
  - a.) Seeking to deflect scrutiny by contending that Congress and the Executive Branch have created a flawed reimbursement system. This argument is specious, because the system works well as long as drug companies tell government insurance programs the truth about their prices. If a flaw exists, it is the fault of the drug companies who choose to give the government false prices.
  - b.) Contending that the inflated reimbursements are needed to defray other provider costs not adequately covered. Some health care providers may be justified in requesting higher reimbursements. The recent GAO study, however, will confirm that the drug companies in question (and I reiterate that not all drug companies are guilty of this practice) have generated exorbitant reimbursement schedules for certain drugs. The scheme benefits only the companies and their provider customers, to the detriment of government health insurance programs and patients. These inflated reimbursements are created only when a drug company desires to fend off competition; they are not calculated to cover administration costs, and they far exceed any reasonable level of reimbursement.
  - c.) Some health care professionals have stooped to extortion tactics by threatening that they cannot continue to care for cancer patients if their gravy train is derailed. The false premise for this threat is revealed by the fact that those same health care professionals were making the drugs available to patients before manufacturers contrived to create such lucrative "spreads" to stave off competition by other manufacturers.  
I find it offensive that the drug companies that are engaging in these practices have tried to conceal their actions while at the same time piously holding themselves out as stewards of the public good. In fact, the sub-committees' subpoenaed records reveal that one major drug manufacturer inflated price reports for a broad range of cancer drugs while touting itself as America's "most admired" pharmaceutical company.
- 7.) The federal government and many states have taken action to improve reimbursement systems by requesting additional price data. For example, California often bases payments on manufacturers' reports of direct prices and submission of manufacturer invoices; Texas requires written certification of different kinds of prices and costs; many States rely on reports of Wholesaler Acquisition Cost rather than AWP; HHS regulations were modified to provide for a federal Med-

icaid Upper Limit; and Congress enacted the Medicaid rebate law. Each of these efforts, however, has been circumvented and frustrated by certain drug companies that falsely inflate any form of price or cost data the government attempts to use to set reimbursements.

- 8.) The fraud scheme deprives government programs of the benefits of vigorous price competition that occurs when expensive drugs become subject to competition by generics, other patented drugs, or other kinds of treatments. Prices drop in the marketplace, but prices reported to the government remain at the same level, or rise. As a result, Medicare, Medicaid and the public are misled to believe that the drugs remain highly expensive when in fact they sell for a fraction of their pre-competition prices. The current example of the cancer drug Taxol is illustrative. When Taxol's patent protection expired recently and a competing generic drug entered the market, the prices of both drugs began to fall. Nevertheless, the reported prices remained at the pre-competition level, creating a "spread" that is used to market both drugs, and government health insurance programs have not benefitted from the reduced (but unreported) prices set by the marketplace. It is ironic that there was no "spread" before Taxol had a generic competitor, but now a "spread" exists and is used to market both drugs.
- 9.) Those drug manufacturers making false price representations have effectively usurped the right and the duty of Congress to determine Medicare drug payments, and the right and duty of state legislatures and Congress to determine Medicaid drug payments. Increased oversight by the Congress and enforcement by the Executive Branch, have resulted in at least two drug manufacturers reporting markedly lower prices to the Medicaid Programs, however, even those companies continue to report inflated prices for Medicare purposes.

After concluding the first stage of its investigation last year, Congress enacted legislation requiring the General Accounting Office to investigate and report on the true costs of the drugs in question and the expenses incurred by health care providers in administering them. The legislation also requires the recently renamed Center for Medicare and Medicaid Services (CMS), formerly known as the Health Care Financing Administration (HCFA), to review the GAO report when issued and take appropriate action with respect to Medicare drug reimbursements. State Medicaid programs already have taken actions based on the results of investigations by the Department of Justice and the National Association of Medicaid Fraud Control Units, and many of those programs have already reported saving tens of millions of dollars as a result. I am hopeful, that after considering the GAO report, CMS Administrator Thomas Scully will take similar action to stop these excessive payments that are costing the Nation's health care systems billions of dollars each year.

In conclusion, the evidence amassed by the sub-committees demonstrates without doubt: No drug reimbursement system will succeed unless drug companies tell the truth about their prices. Our existing Medicare Drug Reimbursement System is broken because certain drug companies lack honesty and integrity. Any expanded drug benefit will be doomed to fail if those same companies continue to lie about their prices.

Thank you for the opportunity to bring to the sub-committees' attention this widespread, institutionalized fleecing of Medicare, Medicaid and other health care programs funded by the American taxpayer.

I will be happy to answer any questions the sub-committees may have.

Mr. GREENWOOD. Thank you for your testimony.

The Chair recognizes himself for 5 minutes for questions, and would refer to document N1 and ask the staff to have that projected. That's the document that was projected earlier.

N1. Staff, N1. There we go.

Let me start with you, Mr. Bentley, and let us look on that chart at Mitomycin. Mitomycin is what kind of drug, Mr. Bentley?

Mr. BENTLEY. It's a chemotherapy agent.

Mr. GREENWOOD. It's a chemotherapy agent.

Let me understand—let me make sure that I understand and we all understand this chart. Your company, Ven-A-Care, the one to purchase that drug, at catalog price from the manufacturer would pay \$180. Is that correct?

Mr. BENTLEY. Yes, sir.

Mr. GREENWOOD. Okay. And the Red Book, the document that Medicare uses in order to determine the reimbursement to the physician, then is posted by the manufacturer at \$869.33. Is that correct, sir?

Mr. BENTLEY. That is the Medicare allowable, which would be 95 percent of the AWP that is posted in the Red Book.

Mr. GREENWOOD. So Medicare pays \$869 to the physician for a product that he paid \$180 for—95 percent of that?

Mr. BENTLEY. Correct.

Mr. GREENWOOD. So the overpayment is in the vicinity of 680 some dollars Medicare is overpaying for that drug?

Mr. BENTLEY. Yes, sir.

Mr. GREENWOOD. Now, let us look at the impact of that particular chemotherapy drug on the patient. The patient's requirement under Medicare is to pay 20 percent, 20 percent copay. If, in fact, the copay was based on the—what was actually paid for the product, I would assume that that would be a \$36 cost. Is that correct?

Mr. BENTLEY. Yes, sir.

Mr. GREENWOOD. Okay. Instead, the copayment is \$173.86, which I would calculate is \$137 more than the patient should pay in copayment. So the patient gets ripped off for \$137. And whether or not we believe that the oncologists—and I do believe that the oncologist needs to recover more than we're paying him now. I'm looking at the patient here. What if the patient doesn't have the \$173.86? What if the patient could afford \$36 for the treatment, but doesn't have the \$173. What happens?

Mr. BENTLEY. That's correct.

Mr. GREENWOOD. The patient could conceivably do without treatment.

Mr. BENTLEY. That's correct. Or other family members may have to help pay the successive copayment amount, which only puts a burden on other family members when a loved one has cancer. And I would also say that Mitomycin is also paid to pharmacies by the DMERC's under Medicare, not just oncologists.

Mr. GREENWOOD. Let me pose this question to Mr. Scanlon. Mr. Scanlon, the crux of this whole—there is no question that AWP system is broken. I've talked to every pharmaceutical company that I could find. They all agree. I've visited my own oncology doctors in my county. They agree that the system doesn't—that the system doesn't make sense as it's constituted. There is this question of whether the oncologists in particular and other providers are undercompensated and what we need to spend to pay them fairly.

Is it your testimony that—what was the figure in your report for the overpayment to oncologists for these drugs? What was that number?

Mr. SCANLON. It's approximately \$530 million.

Mr. GREENWOOD. \$530 million—

Mr. SCANLON. Based on the conservative estimate of—

Mr. GREENWOOD. \$530 million per year, half a billion dollars a year just for oncological products.

And, sir, what does your study reveal as to what it would cost to bring oncologists up to the rest of the medical profession in terms of the way they're compensated by Medicare?

Mr. SCANLON. There are a number of elements in that. I mean, to put the oncologist on par with other physician specialties, first of all, there's the issue of the adjustment of their fees for chemotherapy administration and the substitution of an alternative method for the basic method. Restoring the basic method would add about \$31 million to their payments.

Oncologists have also raised issues about an adjustment that HCFA made in terms of their supplies, and they've indicated that they believe that HCFA has reduced their supply estimates too much in terms of taking the drug costs out of what was reported in the survey data used to set up the fee schedule. We don't have a firm estimate of what supply expenses should be. The oncology profession has indicated that it should be about double of what HCFA uses, which would add another \$20 million to oncology payments.

Other issues that they raise, we cannot make an estimate now as to what impact that might have on their fees, and as I indicated, they might not have a big impact at all because other specialties might have the same types of issues, in terms of practice expense, keeping pace with changes in practice.

Mr. GREENWOOD. My time has expired. The Chair recognizes the gentleman from Florida Mr. Deutsch for 5 minutes.

Mr. DEUTSCH. Thank you, Mr. Chairman.

Mr. Scanlon, if I can follow up on that, because I think one of the interesting things in your very, you know, insightful testimony was really this whole issue of the alternative approach. I mean, there's a clear consensus it's broken. How do we fix it? I mean, specifically, if you can elaborate. You were starting to elaborate in terms of the physicians themselves, the reimbursement, the AWP reimbursement. I mean, can you offer some specific suggestions to us?

Mr. SCANLON. Well, in terms of the physician payments for chemotherapy administration and other services that don't involve a physician directly, to restore the basic method, what it means is that you use differences in the resources—the types of inputs—that are needed to provide a different service as the basis for determining Medicare fees. The alternative method that was used by HCFA involved the substitution of historical charges, what physicians actually charge, and which oncologists have said were based on the past and do not reflect current experience or practices in the delivery of these kinds of services. So we believe in substituting information about actual resources that are required, that HCFA has developed through expert panels and may need to update through additional expert panels to keep current, but that kind of information is key to put the physician fees on par with—

Mr. DEUTSCH. If I can follow up on that, your study points out almost a 10-to-1 differential between what government—what we would save or what Medicare would save if we changed up AWP versus switching the physician payment. The oncologist group—and I don't know if they are going to testify to this later, but I'm aware of at least a study that they did, not as extensive as yours, which was saying it was almost a 1-to-1 tradeoff. Have you looked at their study, and how do you respond?

Mr. SCANLON. We have looked at their study. We have not been able to replicate their study, but at the same time we have concerns about the method of the study. I mean—

Mr. DEUTSCH. That is obviously a pretty big differential.

Mr. SCANLON. There is no question about it. There's a number of differences in terms of what we've done and what they have done. We have built this estimate based upon all the services physicians provide, which we think is key to understanding this problem. The physician fee schedule is a relative value fee schedule. It sets fees for one service based on the comparison of the resources required for it versus other services, and it distributes an amount of money that we found to be adequate in order to get physician participation in Medicare. So that's the criteria for setting physician fees.

To build an estimate of expenses from looking at individual procedures is not nearly the same, because what it ignores is the fact that the fees that become paid to a physician includes three components. One is the practice expense component. The second one is the physician work component, for which there is no comparable sort of accounting cost, and that accounts for over half the fee. And the third thing is the malpractice expense component. So in some respects it becomes—when you start to look at this as a piece, you have the potential of being misled, and it's much more important to look at this in the aggregate.

Mr. DEUTSCH. If I can sort of open this up to each of you individually, and let me also welcome Mr. Bentley as a constituent. I'm glad you made your way up to Florida. It's not as easy—from Florida. It's not as easy as it used to be. Hopefully that will change.

But in my opening statement I mentioned what I think in some ways is as big, if not the biggest, concern is the substitution based on market forces, and we all can, you know, come up with theories that it's going on. Do we have empirical or even anecdotal evidence that, in fact, there has been substitution based upon the increased spread of particular drugs? I mean, do we have either anecdotal or empirical evidence, besides theoretical evidence, which clearly we do have? If you don't know, that's fine.

Mr. BENTLEY. I believe there is evidence that—

Mr. DEUTSCH. Can you point to anything specific that you're aware of?

If you can pull the mike closer as well. It gives—I mean, we can all see that it should be occurring, or it could be occurring. Obviously we hope it's not occurring.

Mr. BENTLEY. This was part of a drug I was referring to in my opening statement, which is a new version of an older drug called Vepesid, which is—

Mr. GREENWOOD. Mr. Bentley, why don't you lift your microphone up. I know everyone wants to hear you. And make it—speak as directly into the microphone as you can. Point it toward your—

Mr. BENTLEY. Okay. This is an internal Bristol-Myers Squibb document that shows Etopophos, which is a second-generation etoposide that was developed, and they say that it's clearly superior to that of etoposide and for various reasons. And then they go on to the next document, where it says, the Etopophos product pro-

file is significantly superior to that of etoposide. Now, what they were concerned about was there was a big spread already in etoposide, so how were they going to market and sell the better, in their own words, clinically superior, second-generation drug?

Now, they admit right here, currently physician practices can take advantage of the growing disparity between Vepesid—that's etoposide—list price and subsequently the average wholesale price, AWP, and the actual acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physicians' financial incentive for selecting the brand is largely diminished.

And they go through some different scenarios. And I can tell you right now that the spread differential on etoposide, as was pointed out earlier, Medicare is reimbursing approximately \$135 for the old version of etoposide, and it costs less than \$10. And literally we have a, quote, clinically superior drug that Bristol-Myers Squibb has been unable to market because of the spread on the older version of the drug.

Mr. GREENWOOD. Your time is——

Mr. DEUTSCH. Can I just ask a very short follow-up question?

Mr. BENTLEY. Sure.

Mr. DEUTSCH. And I know my time is expired. I guess I have a copy of this, and it's up there. I'm just curious. You were able to ascertain this information through your whistleblower lawsuit. How were you able to——

Mr. BENTLEY. This—I obtained this from the Justice Department, cooperating with them. They obtained this by an OIG subpoena issued to Bristol-Myers Squibb.

Mr. GREENWOOD. The time of the gentleman has expired.

The Chair recognizes for 10 minutes the gentleman from Florida, the chairman of the Health Subcommittee, Mr. Bilirakis.

Mr. BILIRAKIS. Thanks, Mr. Chairman.

Mr. Bentley, the Mitomycin that's on that chart, 40 milligram, and the dollar figures attached thereto, how many doses is that? Is that one dose?

Mr. BENTLEY. Well, that's one vial. Depending on how it is administered, that could take two or three vials to equate to a dose.

Mr. BILIRAKIS. All right. So if it took 2 or 3 vials for one dose——

Mr. BENTLEY. You multiply all of those figures times 2 or 3. And if I can interject to shine some light on some previous remarks that were made, the Mitomycin, that AWP, that was established by the drug manufacturers, and that is what Medicare is relying on to determine the reimbursement. And I can tell you I have examined tens of thousands of internal drug company documents, and there is not one scintilla of evidence that shows that the drug companies established an inflated price for Mitomycin in order to offset practice expense for oncologists or to give the pharmacists any more money. It just—that is not the focus.

Mr. BILIRAKIS. So who created the AWP, then? Is it created by HCFA, by HHS, by——

Mr. BENTLEY. It's been around, sir, for the better part, that I'm aware of, about 40 years. And for a great number of those years, it's always worked, and there are still a great number of companies, Merck, Lilly, Johnson & Johnson, DuPont, who do not engage

in this type of gaming the system. When they make a representation about the price of the drug, you may not like it because it may be high, but that's the price they sell it for.

Mr. BILIRAKIS. Let me ask you, about the \$180 figure which is the Ven-A-Care cost. Is HCFA, in your opinion, aware that that's really all that it cost?

Mr. BENTLEY. I think they are now, sir.

Mr. BILIRAKIS. Mr. Scanlon, are they aware of it?

Mr. SCANLON. Yes, Mr. Chairman.

Mr. BILIRAKIS. Have they been aware of it?

Mr. SCANLON. They have been aware of it, and last year they did take steps to try and change this, but then because of concerns raised by providers, they backed off and——

Mr. BILIRAKIS. Concerns raised by providers to HCFA?

Mr. SCANLON. About the imbalance between the drug prices and the drug administration compensation.

Mr. BILIRAKIS. Concern was raised by providers, being——

Mr. SCANLON. Yes, sir.

Mr. BILIRAKIS. [continuing] let us say in that case the oncologists?

Mr. SCANLON. Yes, sir.

Mr. BILIRAKIS. Mr. Grob, do you agree with that?

Mr. GROB. That's correct.

Mr. BILIRAKIS. Because concerns were raised by providers, it just remained status quo?

Mr. GROB. The status quo has remained. In fact, the Congress required that it remain that way.

Mr. BILIRAKIS. That's what I want to get to. The Congress did what?

Mr. GROB. The Health Care Financing Administration had advocated making available more realistic drug prices to the carriers, but because of the concerns that were raised, the Congress placed a moratorium on any reductions in those prices, and it commissioned the study of the General Accounting Office.

Mr. BILIRAKIS. And that's what we have today. I'm almost speechless.

Is there a substitute or an equivalent drug that will do the same job Mitomycin will do? Mr. Bentley?

Mr. BENTLEY. I'm not a pharmacist. I'm not—I don't know. Really my expertise is on pharmaceutical pricing and the economics.

Mr. BILIRAKIS. Do any of you know?

Mr. GROB. I don't know, Mr. Chairman.

Mr. SCANLON. Nor do I.

Mr. BILIRAKIS. Mr. Grob, do you know, can HCFA, the administration, HHS, et cetera, et cetera, can they fix this in a way that it should be fixed? You know, and I'm not—I realize this is more complex. It's certainly not a simple situation, but can they fix this? Do they have the power to fix this, or does it have to be Congress?

Mr. GROB. Theoretically, CMS does have the power through an authority called their "inherent reasonableness" power, which allows them to conduct studies to determine what the true prices are, and if there is a price that is, as the phrase says, inherently unreasonable, they can reduce it. However, that's a very lengthy process to conduct the studies. The studies are almost——

Mr. BILIRAKIS. Yeah. But then we get the figures up there, the 7 cents for the one and 94 cents for the \$1.20. What kind of studies are we talking about?

Mr. GROB. Well, they would be studies to determine what the market prices are, what comparable prices are.

Mr. BILIRAKIS. But those are the prices, aren't they?

Mr. GROB. We believed for some time that there's good, strong evidence for reducing those prices, and CMS would have that authority. And, in fact, CMS had the means even just by making the prices available to the carriers to do it, but there has always been resistance to this.

CMS to its credit in the past had advocated other ways to deal with the high prices e.g., to increase the discount on the AWP, but these proposals—

Mr. BILIRAKIS. I guess my time did expire. I'm sorry, Mr. Chairman. I didn't notice that.

Mr. GREENWOOD. Thank you.

We are going to collect a dollar for the firefighters of New York for everyone who says HCFA for the remainder of this hearing.

Is the gentleman Mr. Brown available for questioning now?

In that case, the gentleman from New Jersey Mr. Pallone. He's recognized for 5 minutes.

Mr. PALLONE. Thank you, Mr. Chairman, and, Mr. Bentley, I just want to continue with some of these documents in an effort basically to show that, you know, companies consider doing what's right, but then they choose to do what's wrong, so to speak. And if I could ask that we successfully look at, I guess, B-1, B-2 and B-3, and we'll start out with B-1, which is an internal Glaxo document. And I just wanted to—you know, Mr. Bentley, if you just wanted to comment on that first document in this regard.

Mr. BENTLEY. Sure. This is very interesting. Glaxo was the first company to market the antiemetic Zofran that's used to control nausea and vomiting in chemotherapy patients. And they had a natural monopoly for a number of years, because they had the only drug that was FDA-approved for this indication. And in approximately 1995, SmithKline came out with a competing drug, not a generic, but a drug that was effectively controlling nausea and vomiting. And Glaxo noticed that their market share declined dramatically right from the onset of the introduction of Kytril. Now, they expected obviously they were going to lose some market share, because there was competition in the marketplace. They didn't expect to lose the amount that they had lost so rapidly. And the marketing department told Glaxo, well, it was an easy answer. Physicians were actually being courted by SmithKline representatives to switch from Zofran to Kytril based on the opportunity to make money from Medicare and Medicaid.

So they came up on some proposals on how they were going to level the field and this was an internal memorandum. Obviously somebody with some conscience in Glaxo was concerned about the ramifications of what Glaxo was proposing to do and that was to raise the net wholesale price in AWP, which would effectively increase the amount paid by Medicare and Medicaid while simultaneously lowering the price to physicians and to specialized pharmacies like Ven-A-Care in order to create a spread to compete with

SmithKline's competing product, and that spread that they were going to compete with was not their own money. It was the government funds being used to fund a kickback essentially for their marketing efforts to compete with SmithKline, and they were obviously very concerned about what Congress was going to look at.

Mr. PALLONE. This was the second document, right, B-2? Oh, we are still in B-1, okay.

Mr. BENTLEY. The next document shows what Ven-A-Care received in the mail from Florida Infusion announcing this great revolution, and that was Glaxo had raised the AWP but lowered the price, effectively creating a spread to induce Ven-A-Care and physicians to go back to Zofran for those that were using the competing Kytril.

Mr. PALLONE. Then let us go to B-3. This is the Smith Kline document where, I guess what is it called, Health IQ, where they talk about possibly turning Glaxo into Medicare and that that might be a reasonable approach but then they worry about the whole industry going down. Do you want to comment on that?

Mr. BENTLEY. Yes. This is interesting because there was actually a series of letters written by Health IQ under the letterhead Physician Home Care Associates, and they were written to every medical director of the Medicare Part B carriers and to the Medicaid medical directors and they were ostensibly representing themselves as this great group that represented home care doctors and pharmacies. However, it was nothing more than a lobbying group that was being paid for by SmithKline, and if you look at bullet point No. 4 it says from the communication received to date the letters received by Physician Home Care Associates, ostensibly written on behalf of physicians and other health care providers, appear to be greatly appreciated by the medical director. That is the Medicare Part B directors. A follow-up letter apprising Medicare of an increasing in Glaxo's AWP and a proffered discount to purchasers which would seem to benefit providers might appear peculiar and prompt questions as to the true identity of Physician Home Care Associates." And then they go on that they—

Mr. PALLONE. Read that next section.

Mr. BENTLEY. Sure. "As a result of these issues raised above, Health IQ's concern that highlighting the difference between the actual acquisition cost and the published AWP may not only increase attention to Glaxo's pricing practices but may provide the impetus for HCFA to implement a system that could impact not only reimbursement of anti-infectives but all pharmaceutical and biological products. The ramifications could extend well past Medicare to include Medicaid programs also administered by HCFA as well as private payers who tend to mimic policies and procedures implemented by public payers."

Mr. PALLONE. Obviously that was the point that they were concerned that the whole industry was going to go down.

Mr. BENTLEY. Absolutely.

Mr. PALLONE. Thank you. Thank you, Mr. Chairman.

Mr. GREENWOOD. Thank you. I recognize for purposes of inquiry the chairman of the full committee, Mr. Tauzin.

Chairman TAUZIN. Thank you, Mr. Chairman. First let me respond to concerns that we have somehow questioned the motives

of any physicians involved in this payment system. First of all, the concerns expressed by oncologists as we have reviewed this matter was to the effect that if we did not simultaneously repair the deficiencies in practice reimbursements under the Medicare system while we are curing the unfairness of the system that reimburses way beyond the cost of the medicines that are provided to Medicare patients that we would be disrupting the provision of health care services to patients in America. That is a real concern of this committee, and so let me turn quickly to the—I guess to the first question for the GAO. The numbers you have submitted to us is that practice reimbursements are about \$51 or so million dollars short; is that correct.

Mr. SCANLON. The adjustments that we think should be made would approximate that.

Chairman TAUZIN. I understand Mr. Scully is going to put a figure of about \$48 million or so. It seems the two of you are close, but even if you multiply the numbers you have given us by three, if you provided reimbursements to the physicians three times what you estimate is a shortfall at \$150 million, we are still talking about overpayments of a billion dollars. So if we correct the overpayment problem in the system because of this artificially high AWP wholesale price posting, there is ample room, then, to correct the deficiencies that you and Mr. Scully have found in the payment to physicians for services; is that correct?

Mr. SCANLON. That is correct.

Chairman TAUZIN. So that in correcting this problem, if we handle it properly, if we make adjustments for physicians' practices three times as much as you estimate is a shortfall, we could still save the system \$850 million or more each year in the overpayments for these drugs; is that correct?

Mr. SCANLON. That is correct, but I would also note, Mr. Chairman, the changes that we have talked about in terms of implementing the fee schedule as you have specified do not involve an additional expenditure because the fee schedule has been budget neutral. If you decide to increase—

Chairman TAUZIN. The problem there is it would come out of other physicians' reimbursements. So if we added to that pool, three times what you recommended as the deficiencies paid to these physicians so that it could be spread out more equitably without denying other physicians their reimbursements, we would still save \$850 million to the Treasury in the—

Mr. SCANLON. You could still save considerable money.

Chairman TAUZIN. Let me turn to the other issue that disturbed me so much, and I want to tell my friends Mr. Ganske and Mr. Norwood that I didn't make these comments lightly and I stand by them. I am looking at the IG report now that is number Q-1. It contains some rather chilling language. It says in that report a review of 22 skilled nursing facilities, that at these facilities \$4.8 million out of the \$9 million in claims, 53 percent were not medically necessary. They went on to say that in addition financial effects we noted about overutilization and overpricing were potentially harmful to the patients. "Medical reviewers who were part of our audit"—this is a quote. "Medical reviewers who were part of our audit concluded that patients receiving unnecessary infusion serv-

ices were placed at undue risk for complications,” and it went on to say, “Furthermore, infusion services are invasive procedures that are painful and when unnecessary reduce the quality of life.”

That IG study, did it not, also went on to say that maybe one of the inducements for this overutilization was this crazy system where overreimbursements were provided for some of these infusion drugs?

Mr. GROB. Again, we didn’t tie analytically the two together, but the thing that concerns me is that it is in the air. I think where we want to be—I think we would all feel better if it just wasn’t that big of a possibility.

Chairman TAUZIN. That is the point. Let me try to say it maybe a little more accurately, as you have tried to say it, Mr. Grob. The fact that these overpayments are there next to the fact that there is evidence not only in that study but in one reported by the New York Times on May 13, 2001 indicating how much overuse of chemotherapy seems to occur in some cases in the last stages of some cancer patients’ lives when there is strong medical evidence that the chemotherapy had no effect at all upon the quality of life or the treatment of the cancer, that these studies standing out there with this overpayment system also present, if nothing else, creates the image that something is wrong and that is bad and the notion that anyone in this country would be given infusion drug therapies that would harm them or could possibly harm them or make life less pleasant for them in those last days with a system that overcompensates for doing that is a juxtaposition that we ought not to permit. Isn’t that a point in your study?

Mr. GROB. It is. We feel that we all wish you would not have to ask me that question.

Chairman TAUZIN. Exactly, and I am going to quote you. Abusive billing arrangements between the skilled nursing facilities and infusion suppliers resulted in tremendous profits, and here is your quote, “which encouraged the overutilization of infusing services when no treatment was necessary.” You did tie it together.

Mr. GROB. Yes.

Chairman TAUZIN. Even if you hadn’t, the juxtaposition of those two elements, overutilization where it could be harmful to patients and make their lives miserable in the last days and overpricing that could possibly encourage it is a situation we should not tolerate; is that correct, sir?

Mr. GROB. That is right .

I think the reason we could say that was in that case we found representatives, nurses from the infusion company, that were screening the nursing home patients as they came into the nursing home. So there was actually a presence there. So it went beyond mere speculation—

Chairman TAUZIN. Again, my apologies to any physician who thinks I may have slammed them. My mother is a three-time cancer survivor. I pray at the altar of this medicine that has saved my mother’s life. So don’t get me wrong. I love any doctor that I know takes his oath seriously and practices it. I defend my own profession, the legal profession, against slams whenever they come unfairly, but I don’t defend unscrupulous lawyers, and I will not defend an unscrupulous system that puts people into this position or

creates this image when it should not exist. So I hope that clarifies it a bit. The bottom line is we ought not create a system that even creates an image that anyone is providing infusion medical services to a patient in those kinds of conditions with any kind of connection to the fact that there is this availability of huge profits involved for doing it rather than the needs of that patient and the wonderful care and concern that almost every doctor I know provides to those patients, and I am talking about the fact that in every profession there could be a few bad apples and we ought not encourage them.

Thank you, sir.

Mr. GREENWOOD. I thank the gentleman, and the Chair recognizes for 5 minutes the gentlelady from California, Mrs. Capps.

Mrs. CAPPS. I have to acknowledge I am struggling a bit to figure out how to pose it. I have two different things I would like to talk about, but I am curious, Mr. Bentley, you gave kind of an autobiography in a way, if you will, of your company in the beginning with the treatments that you provided and then blowing the whistle, if you will, or noticing the discrepancies that you did, and I am curious to know—you were squeezed out of—you opted out of certain partnerships or relationships that were offered to you. What is the status of Ven-A-Care now?

Mr. BENTLEY. Right now we spend most of our time trying to educate and shine the light on what we feel that are abusive practices and abusive reimbursements so that we can hopefully have a level playing field some day and go back and do what we have always done.

Mrs. CAPPS. So you are actually in this business of doing these studies or looking into these discrepancies pretty much full time now.

Mr. BENTLEY. Pretty much full time, yes, ma'am.

Mrs. CAPPS. If I could turn to Mr. Scanlon and/or Mr. Grob, I am sort of anticipating the testimony of the next panel because you have been doing a number of studies that point out what we are all sort of flabbergasted to hear today, to have discovered. To me, and I know all too personally that it isn't coincidental that this is the field of oncology where we have regulating agencies' reimbursement standards that are being set for a field where, because of the investments that the Congress has made in the National Institutes of Health and other research arenas, cancer treatments that were clinical trials 5 years ago are standard today or even 2 years ago. That makes a challenge for a regulating agency to come up with pricing and all of the scheduling, and I would mention also that there have been some discussions about—that oncologists don't have any allowance within their offices for administering for the nursing care that goes into this as well and so some of the incentives for part of our problem come out of what I call the inability of our Medicare and Medicaid organizations to keep up with the changes, and I would like to have your comment on that.

Mr. SCANLON. There is no issue that it is a real challenge to keep something as complicated as a physician fee schedule up to date because we all know that medicine is changing for the better and we would not want to have any kind of system discouraged. At the same time I think the changes are sometimes not as dramatic as

they are portrayed and it is more of an evolution than a revolution, and we can keep data more current and keep our systems more in line.

Now, in this regard, in terms of the physician fee schedule, the Congress stipulated that specialties could provide information, current information, to allow CMS and previously HCFA to update the fee schedule, and some specialties have. The oncologists have not. There are standards for the submission of this information in that the information has to be representative of the profession, it has to be information that is collected from a large enough sample to provide a reasonable basis to proceed forward. That is part of this and I mentioned we were doing another study to see how information can be updated.

Another piece is the issue of how has the delivery of a service changed in terms of the nursing time, other staff time, supplies and other resources? That part needs to be continuously updated as well. There are some mechanisms in place. We will be looking at those to see how adequate they are.

But let me go back to another issue you raised, which is that certain costs are not being recognized within the system. All costs in the data that are available to CMS were recognized. There was the one adjustment in terms of supply expenses but all nursing costs that were in the data that were available were recognized. It is a system that does compensate for some weaknesses by recognizing these costs and then trying to allocate all of these costs across the different procedures. So we have some faith in the system. We have some concerns about how one keeps the data to operate the system as timely as one needs, and that is what we are studying at this point.

Mrs. CAPPS. Just one follow up if I have another minute. You are saying that the discipline of oncology, that those associations of doctors have not been forthcoming with data that you asked for?

Mr. SCANLON. In terms of information that we have asked for, they have provided some of that. In terms of information they could have provided to CMS to allow their fees to be recalculated, they have not done so.

Mr. BENTLEY. May I add to that question?

Mrs. CAPPS. Please.

Mr. BENTLEY. There is a drug that came off of patent, Taxol. It is a very important cancer drug. It has been on patent for approximately 5 years, originally derived from a California tree. So it is now being challenged by generic competition. So you would think the government would start saving some money because there is price competition, and this came across our fax, where this came across May 9, the first generic Taxol is introduced in the market, and they are already touting the spread, and the manufacturer came in with an AWP that was only slightly under Bristol-Myers Squibb's AWP; so the government is not benefiting nor are the patients nor Medicare or Medicaid from the fact that there is price competition occurring. And I question the fact that for 10 years Taxol was on patent and I don't think any oncologist was refusing to give Taxol to patients because there was no spread for those 10 years. When Bristol-Myers Squibb made a representation about the

price, that is what they sold it for. How did Bristol respond to the generic competition?

Here is the next, where you see that Bristol-Myers' Taxol, they lowered their real price in order to meet the competition but they didn't report a lower price to the reporting services, and yet again yesterday I got another fax that now then there is a second generic that has come onto the marketplace and the prices have dropped about another 20 percent in the last 48 hours but yet they put an AWP on their generic, exactly the same AWP that IVAX put on the first generic. So again Medicare and Medicaid and all the private insurers are not going to reap any benefit. And Taxol, the government currently spends, just Medicare, about \$250 million a year on Taxol.

Mrs. CAPPS. It is now standard treatment for breast cancer.

Mr. BENTLEY. Correct.

Mr. GREENWOOD. The Chair thanks the gentlelady and recognize the gentleman from Iowa, Mr. Ganske, for 5 minutes for inquiry.

Mr. GANSKE. Thank you, Mr. Chairman. The area of oncology is kind of a special one as it relates to drug expenses because what one person may say is medically necessary, another person may say isn't. Let me give you a real life example. You have a patient with lung cancer, it spreads to his chest, lymph nodes and to his neck, not a very good prognosis. The oncologist tells that patient, you know, we could put you on chemotherapy, you have a 30 percent chance of responding, and if you do, it may extend your life 2 or 3 months. Now, is that medically necessary or not? And in addition you may not feel very good for some of that time. You know, one person may say I don't think that is—I don't want to do that and another person may say those 2 or 3 extra months with my family may mean a great deal to me that I think is necessary. That is how difficult it is to make some of these determinations.

That said, I think I want to thank this panel for being here; Mr. Bentley, you in particular for some of the data that you provided to us because I agree. I mean I agree with you, Mr. Grob, when you say the average wholesale price is a number that is misnamed. It is clear that we are not getting real numbers and so when you look at—I think this committee should look at the recommendations that you make. We co-authorize a commission to set payment rates. We could calculate a real rate. We could collect the invoices and do a real number if that is what we want to do. But I think there is a bigger question that this committee should look at, and that is do we want to continue in this way and what are the options? What are the options if the Federal Government is going to pay for these drugs? Well, we co-pay at cost. We could just pay what the invoice says. I mean does anyone want to do that? What are the controls on that? Then you can get any type of cost you want.

Okay. We could pay at any true average. That is where you have had it in terms of your recommendations. Well, what do you do about then a large purchaser who is able to get a discount off that true average vis-a-vis a smaller purchaser who doesn't have that kind of leverage?

And finally, you know, we could just set the prices and, quite frankly, I think if you chose the first option of paying at cost, that

is exactly what the Federal Government would do because that is what it has done on every other aspect of Medicare. So I think that whenever we are looking at simply paying at cost or coming to a true average, we need to think about this big picture here as well. My personal preference at this time is we need to reform this, we need to get the actual numbers and then somehow take into account the fact that you can't ask certain smaller purchasers to actually take a loss if they cannot achieve the average, and I am not sure exactly how we do that.

Mr. Bentley, do you have any comments?

Mr. BENTLEY. Well, I would like to say that the prices that we have provided to the committee we think represent those that are available to an extremely small provider. Ven-A-Care virtually has no buying power, and yet there are much better prices for large purchasers and so what we are showing you is just the disparity that is occurring between the reimbursement prices and what a very small provider is very able to acquire these drugs for.

Mr. GANSKE. So do we throw out the AWP or actually make it into a real AWP?

Mr. BENTLEY. There are a lot of drug companies that think AWP really means something and when they make a representation about their average wholesale price that is effectively what it is.

Mr. GANSKE. So for those who are playing the game honestly, it shouldn't affect them that much?

Mr. BENTLEY. That is correct. And in fact I don't think you have physicians that are saying we are not going to prescribe or dispense Lilly drugs or Merck drugs because there is no financial incentive or inducement for us to provide those drugs. I am not aware of any evidence of that.

Mr. GANSKE. Mr. Scanlon, have you looked over the IG's recommendations? Do you have any preference in terms of this list of ways we could go?

Mr. SCANLON. I think taking into account market prices, which is to recognize the average price being sold, is important. Whether it needs to be at the average or somewhat above, to recognize that there may be small purchasers who cannot obtain the average is the key. And we think that the data that CMS has available would allow us to look at that. We did look at small physician purchasers in terms of prices they could get and we did a survey of them and among the ones that responded and gave us prices, they all could get prices that were as good as the discounts that were reported, which are catalogue prices, and these catalogues are something that any physician can buy from.

We talked about it as a starting point and the Inspector General has talked about it. If you are willing to use the catalogue and pay that price, you will get it. If you negotiate, if you can deliver some volume, you may get a much better price. I don't think we are in a position where we want to begrudge the providers that get better prices and say we have to find a way to get it down to the absolute minimum. We are more concerned about the system that is out of control at the other end—the price that is being paid by Medicare—which is so far and above the price that is actually being paid by even the provider getting it at the highest price.

Mr. GANSKE. Thank you, and thank you, Mr. Chairman.

Mr. GREENWOOD. I thank the gentleman and recognize Mr. Burr for inquiry.

Mr. BURR. Mr. Scanlon, is this something that we have just realized for the first time that Medicare pays too much for prescription drugs?

Mr. SCANLON. As Mr. Grob indicated, the Inspector General has been looking at this for a long time and the conclusion has been the same.

Mr. BURR. Why haven't we fixed it?

Mr. GROB. We started it in the mid-eighties but we intensified our work a few years ago, in 1997, and we have issued updated studies every year since then.

Mr. BURR. Why haven't we fixed it?

Mr. GROB. I can't hear your question. I am sorry.

Mr. BURR. Why have we not fixed it?

Mr. GROB. There have been impediments, including a legislative impediment.

Mr. BURR. It would actually require a legislative fix?

Mr. GROB. I believe that would be better—

Mr. BURR. Could HCFA have made changes in the past?

Mr. GROB. CMS could have used its inherent reasonableness authority to do so. It could have obtained better data and made it available. It has tried to do that.

Mr. BURR. Have you ever looked at any other area of Medicare reimbursements and found that people game the system?

Mr. GROB. Yes.

Mr. BURR. All areas? Some areas?

Mr. GROB. Very many areas.

Mr. BURR. As a matter of fact, we reacted to a number of them when we did BBA 1997—

Mr. GROB. Exactly.

Mr. BURR. Did we get them all right?

Mr. GROB. We made a lot of them better.

Mr. BURR. But we got some wrong?

Mr. GROB. I don't know which ones you have in mind.

Mr. BURR. Because in essence we try, like HCFA did, to calculate what a proper reimbursement is based upon the delivery of a product and that delivery can change based upon geographically where you are in the country, what the rental rate is. There are a lot of factors that come into play?

Mr. GROB. Exactly.

Mr. BURR. You from the standpoint of the Inspector General's office have come up with nine suggestions as to how we fix it. I will attempt to refocus everybody here on the solution because I think that everybody here is in agreement that we have a problem.

Mr. GROB. Yes.

Mr. BURR. That the average wholesale price is flawed, that we have lived with it for way too long, that we have not shown the backbone within the agencies that have jurisdiction over it that could have done it or within the halls of Congress where we could have legislatively fixed it. For whatever reason let us put that behind us and all agree it is wrong. You have come up with nine suggestions. Are there any of those that you would highlight more than the others?

Mr. GROB. Yes. I like the idea of the commission, and that is why I put it first. Another one I think would be good would be to use the manufacturer's price that is used in connection with the Medicaid rebates as a source of data. I think it might be more helpful if I could give a few general principles that——

Mr. BURR. Go right ahead.

Mr. GROB. I would agree that I don't think we need to have the bottom amount. I think, as several have mentioned, there is room for some play here. I don't think we should base it on cost. What we have done basically with Medicare is move completely away from that. Hospital payments were based on cost and we had double digit inflation. And then there was Medicare physician payments, and we had very high inflation; so we went to a fee schedule. We have just gone to a fee schedule in the form of prospective payments for nursing homes, home health, and other types of facilities such as outpatient hospital costs. We have learned our lesson. If you go on cost, the actual cost an individual has occurred, you immediately come across two problems. One is looking over everyone's shoulder as they write every check wondering exactly what it is. And you can never keep up with it. And then if you actually could succeed, then no one would care what their costs were because they would get reimbursed for them, and that would drive the prices up.

So cost based reimbursement has been the bane of Medicare since its existence and we have gradually corrected it in almost every area. So I wouldn't base it on the actual cost the person has incurred. I would substitute some kind of a Medicare payment rate which I think has to take into account primarily what the market is. We have to have some sense of what is going on out there in the market. That could be obtained from something like the actual manufacturer's price that, the data that is submitted for the Medicaid program.

Those dollars are available. They can be audited. They need a little definition. You could do some market surveys, and I think that periodically, once a year or so, maybe more frequently, there can be a price set, and then that is the price. I would agree with what you are saying here. I don't think we look over a doctor's office and say you can never make a penny on every piece of gauze in your office. We know there is some give and take. I think people just don't want it to be very big or be a source of gaming and incentivizing.

Those are some general principles. And out of that you could choose one or more of those options, none of which would be perfect, but they all would be better than what we have.

Mr. BURR. Let me mention—Mr. Scanlon can comment on it and also Mr. Bentley—these highlighted solutions to fix an AWP.

Mr. SCANLON. I concur with Mr. Grob, relying on the market. This is one of the few instances where Medicare may be able to rely on the market and what other purchasers are doing. Normally Medicare is such a dominant purchaser that to say we are going to pay what other purchasers pay would distort the market. But in the case of prescription drugs right now Medicare is paying for a very small share of them and they are easily defined commodities. So you are able to specify what you are getting and you are able

to look to other purchasers and what their experience is. CMS has access to the information it needs. It doesn't just need an average price. It needs to know the circumstances under which buyers are getting different prices to be able to set a fee that is going to be adequate so that purchasers in different circumstances are able to buy drugs and supply them to Medicare patients.

So using that information, which is market driven and therefore I think a reflection of the efficiencies of what a market can produce, is key here to setting market prices on a more rational basis.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes——

Mr. BENTLEY. Could I just comment briefly?

Mr. GREENWOOD. Yes, sir.

Mr. BENTLEY. I would like to add that the hallmark of any change in reimbursement system has got to be some truth and honesty from the drug manufacturers because without that any system you go to is going to be doomed to fail, and I point to a number of Medicaid programs who do not use representations of AWP to formulate reimbursement decisions. They use wholesaler acquisition costs. California for 12 companies uses manufacturers' direct prices. There is also cases where in some States they are actually using invoices that are submitted by providers. So if you have manufacturers who are willing to make false statements about the wholesaler acquisition cost, about the direct prices they are selling it to, trumping up invoices so that provider submits an invoice for a thousand dollars when in 30 days they receive \$500 worth of free goods and so they really paid \$500, any system is doomed.

Mr. BURR. Clearly I think the panel would agree, and I appreciate the Chair's indulgence, that we have the tools available to us to fix the average wholesale price. The question is do we have the willingness to fix the average wholesale price? No matter what we choose, whether it is option one or nine, we will still be susceptible to people who find a way to game the system; correct?

Mr. BENTLEY. Absolutely.

Mr. BURR. We will still need an Inspector General to help us on that.

Mr. BENTLEY. There has to be consequences for those who choose to break the law.

Mr. BURR. We can do better than what we have. I thank the Chair.

Mr. GREENWOOD. The Chair thanks and recognizes Mr. Stearns.

Mr. STEARNS. Thank you, Mr. Chairman. I want to lead off with the comment that Mr. Burr mentioned that there has to be consequences. I wonder if the staff could put up on the screen document number F-2, which is dealing with Bayer Pharmaceutical Division. Let me say while we are trying to find it that this is an internal company e-mail that states—in talking about their competition, it is a an e-mail that says, "Chris, if Baxter has increased their AWP, then we must do the same. Many of the whole care companies are paid based upon a discount from AWP. If we are lower than Baxter, then the return will be lower to the HHC. It is a very simple process to increase our AWP and can be done overnight. Let us talk about this at our meeting at Old Saybrook."

So there we have it pretty clear that Bayer Pharmaceutical Division in this case is working to increase the AWP not based upon scientific evidence but based simply upon trying to work out that they get paid more, they give the medical providers incentives, and of course it works out that the wholesaler gets paid more too. So everybody makes it and this continues to go forward.

Let me ask the staff to put document number 7. This is a document from Baxter. I just read one from Bayer and now I would like to read one from Baxter, where they are talking about the AWP and they are saying "This price is being promoted by certain manufacturers' sales forces as a financial incentive to use their product."

So here again we have Baxter Pharmaceutical as saying we have got to get on board here because people are using this as a financial incentive to use their product. They go on to say, "The deliberate manipulation of AWP or WAC prices is a problem that we need to address. The spread between acquisition costs and AWP/WAC is a direct profit for customers and is being used to increase product positioning in the market by certain manufacturers."

So I thank the staff for these documents and I obviously thank the staff for what they are doing here and you, Mr. Chairman, and the chairman from Florida, Mr. Bilirakis. But on a larger note, Mr. Burr touched upon the idea of what can be done. One of the things that can be done is to have the Justice Department enforce under the antitrust rules what has been accomplished simply in this memo.

Now, this was not a big, big problem at Medicare until the nineties, but this has been going on for almost a decade. So in a larger sense Medicare, HCFA, has been a little bit asleep at the wheel because they don't necessarily—I mean I don't think you can blame Congress totally here because they could have done something like Medicaid is doing. Medicaid did something on their own to establish a new AWP system where the rebates will be based upon a more accurate model.

So I think, you know, when you come to these hearings, and I have been to a lot of them and it is almost numbing to see these things, there is a lot of blame to go around, but I don't think Congress is totally at fault. I think HCFA should have done something about this in the early nineties, and obviously I think the Justice Department should have taken examples where Baxter and these other pharmaceutical companies were in collusion in trying to raise AWP without any reason other than to increase the spread for their medical providers to give them incentives.

So I am always a little bit nonplused to sit here and we talk and talk and I say where is there someone that is going to take some action on this.

Another question I have for you, Mr. Grob, you mentioned that we could save as much as a billion dollars a year if we stopped this.

Mr. GROB. I believe at least a billion.

Mr. STEARNS. That goes to a larger question that President Bush has mentioned that he wants to reform Medicare to give pharmaceutical help to those who are poor who need this. So here the government is squandering a billion dollars a year and this could be going to beneficiaries who can't afford pharmaceutical drugs. So this is an area where this whole package of reform is what Presi-

dent Bush has talked about in the campaign and in the presidency. With a simple quick decision by HCFA to move to the Medicaid position on this, wouldn't that solve it immediately?

Mr. GROB. The Medicaid program is complicated and has two features to it.

Mr. STEARNS. One of your recommendations—but instead of Congress sitting here and debating this thing, we go through the subcommittee and the full committee and the House, what can HCFA do tomorrow to make this so that we stop this?

Mr. GROB. CMS would have its options limited to obtaining the most accurate market data it can find and making it available to the carriers in setting their prices and reducing them.

Mr. STEARNS. Well, couldn't they say every pharmaceutical has to give us your wholesale price, certify it, and if it is incorrect, you will go to jail? Is that—

Mr. GROB. We basically have almost the equivalent of that in the Medicaid program, which is why I brought that up. Because of the rebate program the manufacturers are in fact required to submit that data, the manufacturing price we will call it, to the government, and that data is available. Now, if there were legislative authority to use it, that would probably be the quickest fix.

Mr. STEARNS. Okay. Mr. Scanlon, anything you would suggest?

Mr. SCANLON. We believe very strongly that using the data that is available through the Medicaid rebate program would be the quickest vehicle in terms of trying to improve this pricing because it is data that details what manufacturers are selling drugs for under different circumstances. There are statutory requirements here and Medicare under the Balanced Budget Act must pay 95 percent of average wholesale prices. Whether that has to be this fictional price in terms of what is reported in the Red Book for some manufacturers or whether it can be actual average wholesale prices is another issue, and that is where I think reasonableness authority would be something that the agency could do.

Mr. STEARNS. I want to conclude my statement, if I can have additional 30 seconds in my conclusion here, Mr. Chairman.

Mr. GREENWOOD. Without objection.

Mr. STEARNS. Mr. Bentley sent to Dr. Bruce Vladek a memo on June 12, 1997, in which he outlined all of this, and I would say, Mr. Bentley, there has got to be a place for you in the pearly gates up there and if you have any trouble after this hearing call us because we are with you 100 percent and appreciate what you have done. But I would say to the former Administrator what we have here from Bentley's memo here, which is part of the records I believe, shows that we have a scandal like we had with the \$400 toilet seats in the military, we have the equivalent of that here in HCFA, and I think Mr. Bentley actually showed this photograph to the head of HCFA back in 1997, saying, look, your legacy is going to be the \$400 toilet seat, that this is going to apply to this whole problem dealing with AWP.

Thank you, Mr. Chairman.

Mr. GREENWOOD. Thank you, Mr. Stearns. Each of the members has had an opportunity to ask—except for Mr. Green from Texas, who joins us now and is recognized for 5 minutes to inquire.

Mr. GREEN. Thank you, Mr. Chairman, and I appreciate the appearance of our witnesses simply because those of us who are moving in and out and representing Intercontinental Airport in Houston with Continental Airlines, obviously we have a much bigger issue, but I am glad this postponed hearing is taking place, and the issue I think is so important because of the criteria that, Mr. Grob, you talked about in your testimony, and in your testimony you referenced the considerable savings that the Medicare program can recognize if they utilize Federal Supply Schedule as the basis for prescription drug benefits or reimbursements. A number of us in Congress have been advocating this approach for years, not only for the few prescription drugs we provide for under Medicare but for prescription drugs for seniors as a whole.

Now I know in this issue seniors may pay more for their 20 percent co-pay based on this pricing aberration, but generally overall would you say that the high cost by using the Federal Supply Schedule would benefit not only the issue we are here today about but also seniors in general who may not have a prescription plan as part of Medicare?

Mr. GROB. On the surface it would certainly seem to provide a lower cost for the beneficiaries. But I would really have to say that that really is beyond the scope of other studies that were done because there would be other ramifications concerning the market, and so I would say on the surface it would have that effect, but what the other effects are we haven't studied.

Mr. GREEN. I understand. I was looking at your statement. Again I think we have made that issue here in the committee a number of times and just by using the Federal Supply Schedule we cannot only save the Federal Government maybe a billion dollars under Medicare but how many billions do you think we can save the average senior citizen who—

Mr. GROB. If you were to use the Federal Supply Schedule amounts for the drugs that we looked at, you would save almost \$400 million a year for the beneficiaries.

Mr. GREEN. That is just on the oncology—

Mr. GROB. No. We looked at 24 drugs and I think it was about \$350 million or more of savings for the co-payment for Medicare beneficiaries for the 24 top selling drugs in Medicare, top drugs. That included inhalation drugs.

Mr. GREEN. That is for the co-payment for those 24 drugs?

Mr. GROB. Exactly.

Mr. GREEN. I know neither of us can extrapolate too well but if we would provide that to the gamut of pharmaceuticals that seniors have to pay that is not subject to a co-pay, they just—if they are under regular Medicare, they go down and buy their prescription from their doctor, and the Federal Supply Schedule is much less than what I may go down to buy at my pharmacist or my sister or mother or father may do.

Mr. GROB. Exactly.

Mr. GREEN. Mr. Scanlon, you admit in your testimony that the oncologists are often underpaid by as much as 15 percent, and you stated that if we modified the practice expense payments on college practices it could increase their reimbursement by 8 percent, or \$31 million. You also reference a modification of the formula used to

calculate supply expenses, which would increase oncology practice expenses by about \$20 million. I understand that the Medicare statute requires that any changes to the practice expenses for one specialty be budget neutral, therefore if we increase oncology payments we would have to cut payments from another specialty, and I guess that is—I know I followed my chairman a little bit. If we are going to save maybe upwards to a billion dollars in Medicare and we should reimburse oncologists 15 percent, can that come out of savings or are we going to have to take it from cardiologists or other reimbursements?

Mr. SCANLON. It is your decision whether or not you want to add to the pool of dollars that are being paid physicians and whether it is going to come out of the savings. One of the important things to remember here is that the budget neutrality principle was applied at the very beginning, so therefore when the oncology fees were calculated, and they are \$51 million less than what they would have been if a different method would have been used, and that \$51 million was then spent on other specialty services. And some of that \$51 million was also earned by oncologists because some of their physician services had higher fees associated with it, and the \$51 million in terms of the overall physician fee schedule is about two-tenths of 1 percent. So we are talking about a redistribution of a very small amount of money.

Mr. GREEN. But your testimony is we wouldn't necessarily by increasing oncology have to decrease other specialties?

Mr. SCANLON. No.

Mr. GREEN. Thank you, Mr. Chairman.

Mr. GREENWOOD. Each of the members has had a round of questioning. There are a couple more points that need to be made. So we are going to go through a second round for those who want to. It is not mandatory.

The Chair recognizes himself for 5 minutes and would ask the staff to bring up chart P-1. I want to go to the question of utilization because we have talked about the way in which savings could be rendered to the Medicare program and overpayments were made just based on normal levels of utilization, but I want to look at ways in which the spread and the false AWP payments can affect utilization, and let us look at this product here, which is ipatropium bromide, which I believe is a therapy for emphysema, and similar pulmonary diseases.

In 1995, when there was no spread on the drug, Medicare paid a little more than \$14 million in that year. As you can see, as each year passes and the spread becomes larger, utilization skyrockets. Today, 6 years later, Medicare pays more than \$347 million, over a third of a billion dollars, for this drug alone.

Mr. Bentley, I am going to ask you if you could further illuminate this issue.

Mr. BENTLEY. Yes, sir. This is an interesting drug because prior to 1995 it was a patented drug with no generic competition and here again, like the Taxol example, once generics came into the marketplace the prices started dropping precipitously; that is, the prices to the providers. However, the government, both Medicare and Medicaid, has not achieved any savings due to price competition and in all likelihood it is kind of a double whammy because

we believe a lot of this utilization is directly attributable to the spread.

A case in point, recently Texas, their Medicaid program, based on some information Ven-A-Care provided for another inhalation drug, albuterol sulphate, where there was a rather large spread——

Mr. GREENWOOD. Perhaps the staff can bring up document P-2.

Mr. BENTLEY. [continuing] cut its Medicaid reimbursement in Texas. Now, they were cutting their reimbursement, so that would affect access to care. I can tell you this. They reduced the prices dramatically that they reimburse under the Texas Medicaid program to the real prices in the marketplace. They have not experienced any access to care issues, and I heard yesterday from an Assistant Attorney General in Texas that not only are they achieving the savings by the reduction in the prices, they have also started achieving about a 20 percent reduction in the utilization.

Mr. GREENWOOD. Mr. Scanlon and Mr. Grob, do you care to offer any comments in this regard?

Mr. GROB. We have done additional work on nebulizer drugs, looking at the utilization of those, and based on 1994 data we found about \$30 million of the nebulizer drugs that were used were drugs that should never be used in combination. We also found instances of amounts that differed from prescriptions. We also had amounts that varied from the Medicare guidelines for these drugs. So we did find improper utilization and inappropriate utilization of these nebulizer drugs when we looked at them. This is primarily albuterol.

Mr. SCANLON. Mr. Chairman, we haven't studied this beyond the issue of pricing, and the pricing gap is the same that we observed, and I would note this is the kind of disturbing pattern that we have been talking about, increased utilization as the spread increases, and I would also note that there is some very aggressive advertising of these inhalation drugs.

Mr. GREENWOOD. Your study, the GAO study that showed roughly built-in savings that we could achieve only assumed the same utilization and it did not, as I understand it, acknowledge savings from more of a dynamic scoring, if you will, that would occur if the spread was not in fact driving utilization. So when given these two charts where we have seen how change in the spread dramatically affects utilization, would it be fair to assume that a billion dollars is a conservative number because without the incentives driven by the spread we would probably see a change in utilization? Is that a fair statement?

Mr. SCANLON. I believe that is a fair statement. We hope it would be a change in utilization driven by overutilization declining as opposed to genuine access changes as well.

Mr. GREENWOOD. The Chair yields back the back his time and yields 5 minutes to the gentleman from Florida, Mr. Deutsch.

Mr. DEUTSCH. You have a very insightful panel in so many ways, and hopefully it is our commitment to follow up on this. I want to focus on something we have talked about a little bit, and that is what can HCFA do and Medicare do without legislative action? The GAO issue today was in response to a Congressional mandate to do a comprehensive report on drug pricing before the Centers of

Medicare and Medicaid Services be allowed to change the payment structure for Medicaid drugs. Now that the study has been done and we have shown that the average wholesale price is flawed, it would seem as if the CMS should be able to go forward and use the catalogue pricing data obtained by the Justice Department as the basis for drug disbursement. Would you agree with that? Is that possible at this point in time?

Mr. SCANLON. I think it's preferable to use the information that's available through the Medicaid rebate program, in combination with the wholesale catalog discount—

Mr. DEUTSCH. Right. I guess the question, though, specifically is, can they do it now without legislative action?

Mr. SCANLON. They can do it without legislative action. As Mr. Grob indicated earlier, they would do it through the inherent reasonableness process, which is more cumbersome and over the years has resulted in very few changes in prices.

Now, you did give them expedited authority in the Balanced Budget Act to make modest reductions on an annual basis of 15 percent in prices. So that would be immediately accessible.

But we're talking about bigger changes here for a number of drugs, and that would take the more elaborate process. Obviously, if you provide them further statutory authority, it's going to expedite things even more.

Mr. DEUTSCH. Right. I guess I would just follow up, though. I mean, knowing the legislative process as well as you do, it's—you know, one of the reasons we delegate issues like this is administratively it's just a lot easier, especially, you know, in hearings like this when we're clear of what the situation is in the world.

Mr. Grob, did you want to respond?

Mr. GROB. I would hope that you would consider legislative action. Our experience has been that for the use of the inherent reasonableness approach that, actually, that has not been a lot easier than the legislative process. For some of the reductions that have been made, for example, for Oxygen, an initial attempt was made to use the inherent reasonableness, but it ended up getting made by the Congress, and that was done pretty effectively and fairly timely. Your point is that every means should be used and to the extent that there are administrative means those should be used right away. But I think the system is so flawed that we need a brand new system.

Mr. DEUTSCH. Well, let me throw it back. As far as you're aware in either HCFA or in HHS directly, I mean, is this something that the policymaker level—has this been presented to policymakers as an option for them to implement these changes administratively?

Mr. GROB. Okay. Sir—

Mr. DEUTSCH. What is the official, you know, sort of response to that?

Mr. GROB. Well, you'll have to follow up with Mr. Scully on this administration, but certainly our reports have been public and have always been written to the administrator of HCFA, now CMS. So they've always been in the mill, and there have, in fact, been, as I've said, some legislative proposals from the prior administration. So I think it's been on the table.

I think the value of this hearing is the dramatizing and the clarification. I think the subject takes intense study, and the work that went into this hearing has provided that, so that the insights are a lot clearer to more people now.

Mr. BENTLEY. If I could add, I believe the problem could be remedied tomorrow if the drug companies that are the culprits who are reporting these false prices contacted first Data bank and Red Book and submitted new prices, honest prices. And I point to the fact that approximately 90 days ago Abbott laboratories did that for Medicaid purposes, and there were a number of very important drugs where they made representations—I'll point to Vancomycin, one gram as an example—where they were representing the average wholesale price of being around \$56 per gram. They were really selling it for less than \$10.

Now, then, for Medicaid purposes, they initiated a new pricing to, First Databank where they repriced some 200 or 300 drugs with fairly honest representations. The State Medicaid programs across the United States started generating the savings immediately from Abbott's representations and from their actions.

So all we need is for these companies—maybe the hearing will be the impetus for them to have a change of heart and report new prices. CMS doesn't have to do anything. Congress doesn't have to do anything.

Mr. DEUTSCH. Let me follow up. Mr. Grob, what about that as a solution administratively? Could you or through—actually through—could HCFA change the definition of the average wholesale price and then just define it in a different way to—in such a way that would basically be the average wholesale price, for that matter?

Mr. GROB. I think the law says “average wholesale price,” and I don't even believe that that phrase uses capital letters. I think the people who voted for that law, everyone who cast a vote for that law, probably thought it meant the “average wholesale price.” So certainly CMS would have it in its authority to define that “average wholesale price” to mean what the English phrase means. And I think then if they could get the data to back that up, use data that's available, then in fact it could be done. And I do agree with what's been said here by Mr. Bentley about the publication of the data.

Now, these companies have had that option for many years. So I hope they do—I hope they do do it very soon.

Mr. GREENWOOD. The Chair thanks the gentleman from Florida. Mr. Tauzin.

Chairman TAUZIN. Thank you very much, Mr. Chairman.

Let me mention a solution that didn't work, so we don't do that one again, the Balanced Budget Act. We said we'd reimburse the average wholesale price minus 5 percent, and we all went, we'll be danged; we saved a lot of money. And the average wholesale price jumped 10 percent the next year. We didn't only not save money; we lost money. That was a non-solution.

A number of members have talked about the effect of this system on the Medicaid programs of America. In the Medicare program, we're talking about drugs generally that are used in three areas, right, and chemotherapy oncology-type drugs, inhalants and some

other specialties like urology. In the Medicaid system, it's wide open, isn't it?

Mr. GROB. Yes.

Chairman TAUZIN. We're talking about all drugs.

Mr. GROB. That's correct.

Chairman TAUZIN. In fact, Mr. Bentley, you brought a chart for a number of my colleague a few months ago. It's document S-2. I'd like to put it up. It's involving the drug Cefadroxil. And I want to look at the Louisiana Medicaid effect. This Cefadroxil—the chart indicates what the spread looks like on this drug in Louisiana, Pennsylvania, Florida, Michigan, Texas and Ohio. Texas and Ohio have apparently done a lot of work, yet the spread is down. They've got the spread, the difference that the State Medicaid program is paying out as opposed to the real price of the drug.

Mr. BENTLEY. Yes, sir.

Chairman TAUZIN. They've got it down to \$16 and \$35. But in Louisiana the spread on this drug, which costs Medicare \$82, because of a Medicaid reimbursement of \$274.50, is \$191. The spread, the extra money made by the system to the provider, is more than twice as high as the—the spread, the additional profit, is more than twice as high as the cost to Ven-A-Care. Is that correct?

Mr. BENTLEY. Yes, sir.

Chairman TAUZIN. Let me turn to—anybody have any idea what this system is costing the Medicaid systems of America?

Mr. GROB. Yes. They spend about \$16 billion a year, and the last time we studied it recently looking at the brand name drugs, we calculated a loss of about a billion dollars for the brand names. Now, we're working on the generic drugs right now, hoping to have a report—

Chairman TAUZIN. So we're talking not just about the billion in savings to Medicare. We're talking about billions in cost to the Medicaid systems of America—

Mr. GROB. Exactly.

Chairman TAUZIN [continuing]. Which is trying to provide medicine for the poorest of our Nation.

Mr. GROB. Exactly.

Mr. GREENWOOD. Would the gentleman yield for a second?

Chairman TAUZIN. Yes, I'll be glad to yield.

Mr. GREENWOOD. So, on average, since the Federal Government pays 50 percent of the cost of Medicaid drugs, would you argue that, if we changed the system, that there's a potential to save minimally now a billion and a half dollars to the Federal Government. Is that a fair statement?

Mr. GROB. I'm sorry. I didn't quite follow.

Mr. GREENWOOD. Given that the Federal Government is paying—reimbursing the State Medicaid programs for, on average, 50 percent of the price, if they're squandering at least a billion dollars additional—

Chairman TAUZIN. The chairman is making the point that any dollars we save to the Medicaid system, 50 percent is a Federal saving. Right?

Mr. GROB. I'm not sure whether the billion is the total of Federal and State or only the Federal part.

Chairman TAUZIN. And it may be much more than a billion.

Mr. GROB. As I said, we've only done the brand names——

Chairman TAUZIN. Let us look at examples of excessive reimbursements with pharmaceuticals by the Louisiana Medicaid Pharmacy Program, one I'm very interested in. If we can put—that chart is up now. And we can look at one drug—Elkins-Sinn's drug called Leucovorin again. The lowest price according to this report, Mr. Bentley, that you've seen in the marketplace, the real price, is \$2.39.

Mr. BENTLEY. We actually prepared this chart a couple of years ago, and that is why there is the discrepancy between the Leucovorin here of \$2.30 and I believe our other chart where it was \$1.25. Leucovorin has actually gone down in price, yes, sir.

Chairman TAUZIN. But the average Medicare price is \$21.70. The Louisiana Medicaid reimbursement is \$50.34.

Mr. BENTLEY. Twice what Medicare was——

Chairman TAUZIN. Twice what Medicare is reimbursing. And, what, 30 times the price of the drug in the marketplace today or more? That's amazing.

And you go down the list. I mean, you see another one that stands out again, Vancomycin, a price then of 3.45. I don't know what it is today. Medicare was reimbursing it at \$9.44. Louisiana reimburses at \$30.43. How on earth are we going to keep our Medicare programs alive if they're being drained at that kind of rate?

Mr. BENTLEY. That's correct.

Chairman TAUZIN. In fact, I've got a quote from the Wall Street Journal about the program in Missouri where they're saying they've got the biggest core cuts in their Medicaid program in history, and it's going to affect the amount they can spend on education and other vital State needs because it's driving the cost of the Medicaid system into near bankruptcy.

Mr. GANSKE. Would the gentleman yield?

Chairman TAUZIN. I'll be glad to yield to my friend.

Mr. GANSKE. Well, Mr. Chairman, we've all in the past been rather amazed at how cagey those Cajuns down there in Louisiana are on the Medicaid program, but I wondered if we could——

Chairman TAUZIN. Well, I don't believe I want to yield to the gentleman if he's going to insult my Cajun but——

Mr. GANSKE. I want to tie this, though, to the point that Mr. Grob made in No. 2, in how, Mr. Grob, you suggested that maybe we ought to look at—in fixing AWP, we ought to look at what Medicaid has done.

Chairman TAUZIN. That's part of my point. That's the last place we ought to go for advice is what I'm trying to point out.

Mr. GANSKE. Well, maybe that's not the case, because maybe Louisiana is an exception over what has gone on with AWP.

Mr. GROB. Can I make an important distinction?

Chairman TAUZIN. Yes, please do.

Mr. GROB. The Medicaid program achieves savings in two different ways. One of them is that they get discounts off of AWP the same way Medicare does, except they generally get more generous discounts. Now, that's not what I was talking about. There's another part about Medicaid, which is the rebate program, where the manufacturers must return money to the Medicaid in light of the expenditures made, and that is the part I was talking about.

Chairman TAUZIN. That can be instructive. I agree with that. But the point I'm making is that the Medicaid reimbursement is still worse than the Medicare. That's the last place you want to go for advice on how to set an average wholesale price for the Medicare program.

And I want to point out something else, too, and that is that if we're going to correct this the obvious place to look for the real numbers is in the real marketplace with the numbers, Mr. Bentley, you provide for us—you've been providing for us as to what Ven-A-Care can really buy these drugs for. I mean, we're talking about reimbursing two categories of services: one, the service, the practice; and the other, the drugs that are used. In both cases we ought to look at the real marketplace, what is the private sector costing these two systems. And the government ought to reimburse close to those numbers.

If we don't—if we are reimbursing \$50 for a drug that costs a dollar and a quarter, you were telling me, Mr. Bentley, what are we, just insane? And are we going to drive these programs to the point where they can't provide the services they were intended to provide for citizens of this country? We entitle this effort. I want you all to know it.

I think Mr. Burr came up with the title to this whole effort we're trying to undertake in reforming Medicare and this whole pricing system and getting more drug coverage for more Americans. We called it Patients First. Patients are last in this program. They're getting killed.

Mr. SCANLON. Mr. Chairman, I just wanted to note that what we are talking about here is trying to use private sector transactions and information to try and set Medicare prices on a more rational basis. The Medicaid program at the Federal level has the requirement that manufacturers turn over to CMS information on private transactions with genuine net prices, not the types of catalog prices that we've been talking about—

Chairman TAUZIN. Well, tell me about Texas. Texas has been trying to do that, hasn't it? Mr. Bentley, aren't you involved in that? Aren't you involved somehow, and isn't Texas going through hellacious problems? And they're probably leading the country in trying to get this straightened out.

Mr. BENTLEY. That's correct. Texas does not rely on prices that are submitted to either of the publication services, Red Book or First Data bank. They actually go to a certification form, and that's sent directly to the manufacturer.

Chairman TAUZIN. They're ahead of the rest of the States, and they're having a heck of time, aren't they?

Mr. BENTLEY. That's correct. And also, unfortunately, when a manufacturer makes false representations about their prices, the Federal rebate program is not making the States whole for the difference. So they are not—the Congressional intent, as I have read it, of OBRA 1990, which was the State Medicaid rebate program, was to give the State Medicaid programs the benefit of the manufacturers' best prices. But if you start out with false prices, even though they're giving a rebate back to the States, the States are not anywhere close to being at the manufacturers—

Chairman TAUZIN. They're taking a lot more than they're giving back. Is that right?

Mr. BENTLEY. That's correct. Yes, sir.

Mr. GROB. One last clarification. What I was referring to in using the Medicaid program is that there is a very rich source of data that the manufacturers must submit to CMS, not to the States, which is their actual manufacturers' prices, taking into account the discounts that have been offered that are maintained confidentially by CMS but that are used by them. That source of data, which is auditable, is already available. It's submitted every year, and it reflects the actual prices that the manufacturers are charging for the retail sale of drugs. All I was saying is that that data could be used as a basis—

Chairman TAUZIN. I agree with you. I'm not arguing that. I think you're correct. I think there's a good wealth of data there.

My time is up. I just want to make the point again, everything we do to correct this problem—and I love the way Mr. Burr focused on that, on the different solutions you come up with, because that's really what we've got to get to. In every way we correct that problem, we're not only going to save the Medicare program this billion dollars; we're going to save the Medicaid programs of the States possibly their life, their function, their capacity to do their job. And 50 percent of those savings will be inured back to the Federal Government, because we have a 50 percent responsibility in those State programs. I mean, this is very well worth doing, and you're helping us, I think, see our way to it.

Thank you very much.

Mr. GREENWOOD. The time of gentleman has expired.

Does the gentleman from New Jersey, Mr. Pallone, seek recognition? The gentleman is recognized for 5 minutes.

Mr. PALLONE. Thank you, Mr. Chairman.

I wanted to ask Mr. Bentley to comment on some documents. I have a series of documents that were obtained by the committee from Glaxo that detail at least part of their marketing strategy around the Zofran market. And we have those. Okay. I'd like to read, Mr. Bentley, parts of several documents and ask for your comments and ask, Mr. Chairman, that the documents in their entirety be placed into the record if they haven't been already.

Mr. GREENWOOD. I believe they have been, but without objection, they certainly will be.

Mr. PALLONE. Thank you.

The first is a memo dated January 31, 1994 in which this—do we have it up there, or should I wait a minute? Oh, it isn't part of that. Okay. All right then. I'm going to have to read this, Mr. Chairman.

The first is a memo dated January 31, 1994, in which this bullet point appears: Telemarketers who could sell the reimbursement issues with Zofran: Example, because of the contract price on Zofran, there is almost a 20 percent spread between doctors' acquisition costs and AWP. With the price of Zofran being most likely higher than Kytril, it will be to the physicians' best interest to continue to use Zofran.

As you can see, Zofran will mean more profit for the physician. Oncologists seem to be more business-oriented than most physicians. This will be an excellent selling point.

Did you want to comment on that?

Mr. BENTLEY. That's correct. Unfortunately, a lot of manufacturers' representatives are going out and marketing their respective drugs not based on the efficacy of the drug but what in fact will put the most money in either the physician's pocket or the pharmacy's pocket, and so you have a case where there's marketing actually going on to encourage the utilization of one drug over a competing drug by using government funds that fund the kickback as a marketing mechanism.

Mr. PALLONE. And how common is this kind of telemarketing?

Mr. BENTLEY. It is very common.

Mr. PALLONE. Okay. Well, the second—

Mr. BENTLEY. Especially with the drugs that are at the focus of this committee's interest. I guarantee you that their sales representatives are out pounding their beats every time they've raised an AWP or they've lowered a price. Just like those Taxol examples, they get faxes out immediately, followed by telephone calls that, hey, our price has gone down in the market. Buy my drug over my competitor's drug.

Mr. PALLONE. Okay. Thank you.

And then, Mr. Bentley, another of these documents dated October 15, 1997, was developed in anticipation that a third drug, Anzemet, will enter this market. And if I could read a section there for you to comment on.

It says, the package insert includes a warning concerning cardiovascular side effects and describes one episode of complete heart block and one death. A bolded precaution supports the warning.

Now, you're familiar with the actual competition in the marketplace between these three drugs that I've mentioned. Would you say that side effects such as the apparent FDA concern about Anzemet play a prominent role in physician choice of drugs?

Mr. BENTLEY. I would think that that would be a consideration, absolutely.

Mr. PALLONE. But, you know, they're still competing with regard to price.

Mr. BENTLEY. That's right.

Mr. PALLONE. I just—you know, it's amazing to me when I see, you know, some of the things that the committee has uncovered. And, again, I want to thank you for all that you've done. I appreciate it. Thanks.

Mr. GREENWOOD. The gentleman yields back the balance of his time.

Does the gentleman from Texas seek recognition?

Mr. GREEN. Thank you, Mr. Chairman. I have just another series of questions for Mr. Bentley.

Mr. Bentley, you provided us with such an unprecedented view of the world of drug pricing, and it's not obviously a pretty one to those of us—who do you blame for this scheme, the drug companies or the providers or maybe those of us who passed the Balanced Budget Act in 1997 or 1996?

Mr. BENTLEY. I think there's enough blame that can go around for everyone. Certainly, you know, right now, as I've said, the manufacturers that are causing these inflated prices, they have it within their power to make the price changes immediately so that the programs can start achieving these savings that are very much needed. I don't know, other than their motives for profits, why they're not doing that.

Mr. GREEN. That's why people rob banks, too, their motive for profit. But later this morning we're going to hear from the American Association for Home Care, which is what your company did. You're a home health care company?

Mr. BENTLEY. Yes, sir.

Mr. GREEN. This witness will say that the infusion companies cannot make money if they don't get the inflated AWP. Is that true of your company?

Mr. BENTLEY. Well, I can't say that was absolutely true, because our company was merely a pharmacy. We worked in conjunction with home health and nursing agencies who actually went out and administered the drugs. And I will tell you this, that in Florida nursing agencies are paid separately for those services. So if there is an issue that a company is not able to hear, again like the oncologists get enough money on the professional side, I think that is a totally different issue than whether there are false prices being reported on pharmaceuticals.

Mr. GREEN. Did any of the groups, whether infusion companies or doctor/providers—did any of these groups go to the drug companies? Have you had any evidence that they asked for increases in the AWP so that they could survive or that—something that was already readily available?

Mr. BENTLEY. Absolutely. There's evidence in the committee's possession. There's a Baxter internal memorandum where they admit that raising their AWPs was a large part of their negotiations with two large national home health care companies. We're looking for it now.

Mr. GREEN. Okay. And that was already—that's in the documents?

Mr. BENTLEY. Yes, sir.

Mr. GREEN. Thank you, Mr. Chairman.

Mr. BENTLEY. Here it is here. Increasing AWPs was a large part of our negotiation with the large home care companies. And, in fact, there's other documents in the committee's possession where there are providers and GPOs that actually go to the manufacturers and say, we're going to buy your drugs, our members will buy your drugs, and the basis is going to be on the greatest spread, and so we're telling you up front that is going to be the prerequisite as to whether we're going to buy your company's drugs or not. If you have the biggest spread, we'll buy yours over your competitor's.

Mr. GREEN. Mr. Chairman, do we have a copy of that memo that was just up? Is that available?

Mr. BENTLEY. Here it is here. H, low price and best spreads. Contract pricing will be evaluated on lowest price and/or best spread between AWP and the contract price for multisource products.

This was a GPO document. However, it was in the possession of a drug manufacturer who turned it over pursuant to the OIG subpoena.

Mr. GREEN. I'd like to see the whole document. I guess that is my concern, because I see quoted, and you said it was from Baxter?

Mr. BENTLEY. No, sir. This particular document was from Gerimed, which is a large group purchasing organization. But it was presented—or it was produced under an OIG subpoena, so I'm not sure which pharmaceutical company, one of the pharmaceutical companies.

Mr. GREEN. So your testimony is that—

Mr. GREENWOOD. Mr. Green, would you yield for a moment?

Mr. GREEN. Sure.

Mr. GREENWOOD. Would you identify the document in your hand?

Mr. GREEN. I was just looking for something that was reflective of this.

Mr. GREENWOOD. Did you give us the document number?

Mr. GREEN. Mr. Bentley must have that.

Mr. BENTLEY. It's probably in this book. I just don't have the tab.

Mr. LOCKWOOD. It's under O. Either 5 or 6.

Mr. BENTLEY. It's 05. It was produced by Dey Laboratories.

Mr. GREEN. So this information is that some of the providers obviously also worked with the manufacturers to game the system?

Mr. BENTLEY. I believe that Dey had this in their possession, because Gerimed had told Dey Laboratories that in order for Gerimed to consider whether their members would purchase Dey's products, they wanted Dey to know right up front that one of the requisites was going to be who was going to provide the biggest spread on their drugs.

Mr. GREEN. Thank you, Mr. Chairman.

Mr. GREENWOOD. The time of the gentleman has expired.

Does the gentleman from Iowa, Mr. Ganske, seek recognition?

Mr. GANSKE. Thank you, Mr. Chairman.

Mr. GREENWOOD. The gentleman is recognized for 5 minutes.

Mr. GANSKE. Mr. Grob, I want to go over your recommendations in a little bit more detail. No. 1 says that we could look at authorizing a commission similar to MedPAC to set payment rates. Quote, it would then be granted authority to require manufacturers to provide them with drug wholesale prices.

Then on No. 2, you say we could calculate the national estimated acquisition costs based on average manufacturer prices, AMP, which you already testified some on, but you go on to say, we believe an initial intensive effort should be made to audit AMP data reported by manufacturers to validate its accuracy.

Mr. GROB. Yes.

Mr. GANSKE. No. 4 says, or we could increase discounting of the published AWP.

The point that I'm getting at is that—or even on No. 6, we could establish manufacturers' rebates similar to those used in the Medicaid. It would minimize manufacturers' incentives to inflate AWP.

But, anyway, the point I want to get at is we have to have accurate data.

Mr. GROB. Exactly.

Mr. GANSKE. Now, you mentioned a little while ago that CMS has data. How accurate do you think that is?

Mr. GROB. They don't have very much. They have some data that has resulted from some work with the Justice Department on a number of drugs that they were able to make available to the carriers earlier. That data is available—some efforts have been made, I think, as Mr. Bentley mentioned, to get some of the drug companies to produce more accurate prices in their public documents, but systematically the best source of data today is that average manufacturers' price, the actual manufacturers' price, which is submitted to CMS every year to be used in conjunction with the Medicaid program. That is the best data that is generally available and is updated, you know—

Mr. GANSKE. Well, how do you know that that's accurate?

Mr. GROB. We know that it's not completely accurate. That's why we said that would have to be audited. I don't know what data we could trust right now, except that with that data there already is a statutory requirement for it to be submitted to the Department. So there is an obligation for it to be done right.

If the manufacturers don't tell the truth there, then they have submitted false data. And the data then—it does come in regularly. So it is much more susceptible to definitions and audits than any other source, which comes from a variety of different sources and doesn't come so regularly. It's the best set that you could work with right now.

Mr. GANSKE. It seems to me that, you know—if you use that set or whatever, you're going to have to use actual—you're going to have to use actual invoices at some point to cross-check.

Mr. GROB. I think that that idea of the commission sort of encompasses that kind of thinking, that basically you would—I think you need a baseline of data, and then, if you want to, you can use sampling or other means in order to make sure it sounds realistic and that it really does reflect things.

What I was talking about earlier—and I wasn't meaning to respond specifically to another comment that you made—I don't think you'd want to do that for each and every payment that each and every physician makes each and every time. I think that would be overwhelming. But I do think that your point is a good one that trying to get some real live market data, at least on a sampling basis, in order to see if what you have is real I think is a good idea.

Mr. GANSKE. I'm very interested in this. Because as Congress looks at providing increased prescription drug coverage for Medicare, one of my ideas has been that we utilize the State Medicaid drug programs and extend that benefit to the qualified low-income Medicare beneficiaries, CLMBs, SLMBs and others. It's clear we need to make sure that, you know, that program is utilizing accurate data as well.

Mr. GROB. That, by the way, is an excellent point I think, for efficiency. Because again—laying aside the other part of the Medicaid, their use of AWP and this kind of thing, which has the same problems if not worse than Medicare in some cases—going back to the single data source, I think the point is excellent, because then you would have one set of data, which the manufacturers are saying is correct, submitting it to the government under a statutory require-

ment, subject to audit and review. It forms a good base case for anything else you want to do.

Now, you could then take that base case, you could, say, make our percentage higher than that, or something lower. You could then test it with some samples. But it gives you a nice centralized piece. When we tried to come up with these ideas, we know that none of them will work perfectly, but we were looking for some practical ideas, something that is within the means to actually do it. That one kept emerging as one of the good starting points, if you will, for data.

Mr. GANSKE. I thank you. Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman.

The Chair thanks the witnesses for their 3½ hours of endurance. Your testimony has been extremely valuable to us, and the interest has been high. We appreciate your contributions. Thank you, and you are excused.

Mr. GREENWOOD. Now we call forth Mr. Thomas Scully, the Administrator for the Centers for Medicare and Medicaid Services; and we thank you in advance for your forbearance. As has been your habit, you have been here for the entire hearing, and probably only adding to the agony of waiting is watching the membership dwindle from 25 to three. But we look forward to your testimony.

Mr. SCULLY. Thank you, Mr. Chairman, Chairman Tauzin, Mr. Brown—

Mr. GREENWOOD. Before you begin your testimony, you're aware, Mr. Scully, that this is a joint hearing between the Oversight and Investigations Subcommittee and the Health Subcommittee, and it is our practice—the practice of the Oversight and Investigations Subcommittee to take our testimony under oath. Do you have any objections to testifying under oath?

Also consistent with the rules of the House and the committee, you have the right to be represented by an attorney. Do you wish to be represented by an attorney?

Mr. SCULLY. I used to be a bad attorney.

Mr. GREENWOOD. So saying, I'll administer the oath.

[Witness sworn.]

Mr. GREENWOOD. You're now under oath, and you're recognized for your testimony.

**TESTIMONY OF THOMAS A. SCULLY, ADMINISTRATOR,  
CENTERS FOR MEDICARE AND MEDICAID SERVICES**

Mr. SCULLY. Thank you, Mr. Chairman, for having me.

I will quickly get to AWP. I'm not sure how much I have left to add after that, but a few ideas I hope.

If I could, just quickly, before I get to that, I just wanted to thank a lot of the—you talked about New York earlier, and I'd just like to thank the New York hospitals who we spent a lot of time working with the last few weeks. I wish we had more people in the hospitals. But a lot of you also don't realize that outside the hospitals in the bottom part of Manhattan there are also a lot of disabled people that weren't getting home health. And since I have a chance to publicly, I'd like to thank the home health agencies. The Visiting Nurse Association of New York was particularly terrific in the last 2 weeks. But I think a lot of the health care problems that

weren't directly related to the World Trade Centers in the southern Manhattan have been dealt with incredibly well by the City, the State and hopefully with a little bit of help from CMS but with a lot of help from some incredibly selfless providers in lower New York.

Second, if I could just before I get into the AWP issue, one issue that I've become extremely focused on the last 2 weeks since I've now been at the CMS about 3½ months has been a problem you're probably going to get to, if not this year certainly next year, which is HIPAA compliance. And I've recently been extremely focused in the last week on the fact that, like it or not, in a year we have to have a completely new coding system put in place for all providers—Medicare, Medicaid, everyone else.

I don't think I've talked about it enough since I've been on the job. I've only recently begun to understand what a gigantic mission that is, and I think it's obviously like Nancy-Ann's mission to focus the industry on Y2K; and my predecessor, I think it's our mission in the next year to focus people on HIPAA. And whether Congress changes or delays the law or not, we could have a debate about that, I'm sure, at a future time. We have a big, big mission in front of us with HIPAA in the next year, and I intend to—in every speech I give and every time I testify or talk about it, if nothing else, raise the awareness of providers that we have a major, major change in the health financing system that we have to deal with outside this.

Anyway, switching back to HIPAA, the one thing I can say to start with—and I'll try not to go through every issue again—is we agree. And my frustration with the hearing, if anything, is that I hope most of the members that were here didn't leave with the idea that CMS all the way back to Bruce Lanakin before has not been focused on this. And the press also may have already left.

I was involved in this in 1991 in the first Bush administration. We tried to fix it, and there's a long track record from 1991 to 1992.

I was very involved, by the way, in Andrews Air Force Base in creating Medicaid drug rebates with Chris Jennings who was on the Hill, President Clinton's most recent—so I have a long history in Medicaid drug rebates.

This whole issue, people have been trying to fix this for years. And back to Secretary Shalala and Nancy-Ann DeParle last year, they tried to fix it. Got an outpouring of screaming from every affected party, appropriate or inappropriate, and then were hit with a Congressional prohibition for a year not to look at it.

So where we are currently at CMS is we're prohibited, until the GAO report that came out today and until the Secretary reads it, is what the law says, we cannot respond to it. Certainly it will take us a while to put out a rule. But also we're required by law to pay 95 percent of AWP.

Now, could I creatively go back and change it? I'm sure we probably could, and we'd be willing to look at that, but I also have no doubt we'd be sued and it's not the easiest way to fix it.

So I'm here to talk about a number of issues today, but one thing I would ask for is I think this cries out for a legislative solution. We're very anxious to work with you on a legislative solution. I

hope we can do it this year before you leave, and we'll give all our staff resources and everything we can to help you fix it. It's an issue that's been around for a long time, and I'm excited that Chairman Tauzin, you, Mr. Brown, Mr. Deutsch and everyone else seem to be in agreement that we need to fix it; and whatever help you need from CMS on a technical basis to fix it, we are very, very anxious to do so.

We have been paying more than any other purchaser for Medicare drugs on an outpatient basis for a long time, and we're determined to get the price down to a reasonable level. What that is, I'll try to give you a few ideas.

In the meantime, I do think, however, the concern—it is a legitimate concern for the providers—is that if you're going to lower—do we always fix the right price in Medicare, which is what we do for providers? Probably not. Do we have the right price for oncologists and their practice expenses? Probably not.

I think at the same time we reduce the prices for the drugs we need to go back and look at oncologists. I think we probably need to look at the ESRD clinics, dialysis centers that also use these drugs quite a bit. Hemophiliac agencies also rely on this to a large degree. DME providers probably have some argument.

I'm not saying they should all have their rates increased, but there is a substantial amount of money to be saved here. And I think at the same time we do that I think we should also go back and look at the base payment rates and make sure there's a balance. I have very little doubt it's not dollar for dollar, as you're aware and we've talked about, but I do think it's appropriate to make sure that, to the extent we can set prices right for drugs, then for practice expenses, then for practice patterns, we should set them right. And I think there's very little doubt they're not right right now.

But in fairness to Nancy-Ann DePerle, my predecessor in the agency, I think this is something the agency has been trying to do for years, and every time it's put its head up, it's got creamed. So we're anxious and excited that many Members of Congress are now aware of it and are interested in fixing it as well.

Let me just talk quickly and give you a couple of suggestions. One is, Mr. Deutsch and Chairman Tauzin both mentioned that this is not just a problem with the Medicare program, it's a huge problem for beneficiaries. And I totally agree. The fact that the beneficiaries pay the 20 percent copayments is a gigantic problem. There are a lot of things wrong with the Medicare problem. There are very few places where beneficiaries feel the inequities of the program as much as they do here. So I think it's important that the chairman focused on that, and I think that we need to focus on that in the fix. Seniors are paying a big chunk of the inequities in the drug payments that we have here.

Second point, 20 drugs account for 75 percent of the spending in this area. So do we have the tools to look at it? We do, and we can talk a little bit about Medicaid and what we have available in Medicaid. The numbers are big, but the number of drugs you're dealing with are relatively small. Single source drugs account for 60 percent of all the Medicare drug spending. So it's relatively narrow. The numbers are big, but the numbers of drugs we're talking about

are relatively narrow. So I think if we focus on this problem, hopefully legislatively, it is very fixable.

A fourth point I'd make is that I think we need to be sensitive. Physicians do in fact—back as far as I believe it was 1997—actually it was 1991 was the first time I believe that then HCFA proposed to have 85 percent of AWP. Then physicians came back and said we can't get it for 85 percent of AWP. And that may be the case. I think it's important when we look at new reimbursement systems that we understand it's not like the Federal supply schedule where the VA sets prices. Doctors actually have to go out and buy this on the market. And while the prices may be outrageous, they actually have to go get it.

So our real issue is to focus on the manufacturers and how we get the money back at the end of the game from the—to the manufacturers—hopefully no game at the end of the day from manufacturers. And it is a legitimate problem that physicians out there around the country can't always get it for less than a certain amount of AWP.

So I think we need to look at the bottom line of what the program is paying without squeezing providers to the point where physicians out there in the real world can't get ahold of it. And I think in our legislative—hopefully legislative fix, we need to look at that.

There are a number of different approaches that you have talked about, and I'll just try to run through a couple of them that I think are possible.

The Federal supply schedule has been mentioned. I think that when you look at the VA and when you look at the agencies, Coast Guard and others in the Federal supply schedule, it's really not an apples to apples comparison. I think that probably wouldn't work. Those are really Federal agencies buying the drugs for direct use in Federal agencies.

Average manufacturers' price, which is the bottom line number that was used in the Medicaid program, and we do in fact have those numbers and they are audited and I think they're pretty solid, but again, by statute they're confidential and we're not allowed to use them. In fact, our Medicare staff doesn't have access to them. Only the Medicaid staff does. So is that a more legitimate number? Absolutely.

I think there may be some problems there, but average manufacturers' price, which GAO seemed to suggest is a very auditable and very reasonable number, I think if you went to average manufacturers' price, you might run the risk of squeezing access to physicians out there in the market trying to buy them. So I think there's a possibility.

I think the Medicaid program has some flaws, but there's a model there, and I'll suggest that in a second.

You've talked about wholesale acquisition costs which I think is a better price than AWP. But, again, AWP is largely air, and I think wholesale acquisition costs may be a little better, but it's still potentially air, and you can raise it and lower it as you like, and I think it's a very—the potential for manipulation of that is relatively high as well. As a short-term fix it might work, but I think there are probably better ones.

People have proposed that we do a survey of market prices, which also might work. I talked to my staff about trying to do a survey of what nursing homes pay, for instance, because nursing home chains usually have—they're not as big as the Federal supply schedule, but large nursing homes, Manor Care, somebody like that frequently buys—you know, has a similar group of patients buying in large bulk volume.

The problem in doing that—and I think that's a possibility—is that you're looking back a year. And obviously, as you can see from the earlier testimony, the prices change by the day, and looking back and doing a snapshot looking back a year at anybody, for us to do a survey of 2000 prices to set 2001 prices is never going to be quite right. So I think that has its flaws as well.

There is a concept similar to average manufacturers' price called average sales price that you could possibly use, but I think a combination of these we certainly could work on legislatively, and I think the bottom line is that the manufacturers know at the end of the day how many units they're selling to Medicare. They know how many we're paying for.

If we can, in fact, require them, as we do in Medicaid, to tell us what the price is and calculate at the end of the year how many they sold to Medicare and what the price is and recover that price and there is a mechanism to do that, I think to find that balance that we end up getting the right price charged us by the manufacturer, while not limiting and denying access to the physicians that are actually out there in the market, potentially in a small town trying to get it, is the mix that we need to find, and I think it's very doable.

Can we do this administratively? I think we probably won't in the near term, because we probably would get sued. We'd certainly prefer to do it legislatively. I think we could. And if Congress doesn't act, it would probably take us a year to a year and a half to do it. It would take a long rulemaking process. I have zero doubt that we'd be sued, because of what the law says on 95 percent of AWP.

So I would strongly, strongly, strongly prefer to work with Congress hopefully in the next month to find a legislative solution that works, that is fair to the oncologists, that is fair to the dialysis clinics, that is fair to the other patient groups involved and that gets our payment back on the right track. Because it's clearly a very messy system we're in right now.

So I know you've had a long hearing already. That's about as fast as I can talk, and I skipped over a whole bunch of other things I was going to say, but I hope—it may be more valuable just to answer questions. But there is zero doubt that the administration, while we don't have the set solution, is extremely interested in working to fix this problem.

[The prepared statement of Thomas A. Scully follows:]

PREPARED STATEMENT OF THOMAS A. SCULLY, ADMINISTRATOR, CENTERS FOR  
MEDICARE & MEDICAID SERVICES

Chairman Greenwood, Chairman Bilirakis, Congressman Deutsch, Congressman Brown, distinguished Subcommittee members, thank you for inviting me to discuss Medicare payment for outpatient prescription drugs. As you know, prescription drugs are becoming an increasingly important component of modern health care,

particularly for Medicare beneficiaries. We are working with Congress to modernize Medicare to cover prescription drugs and provide relief to seniors from high drug costs. In addition, it is clear that the payment system for selected outpatient drugs that are now covered by Medicare is a mess. Medicare now pays more than many other purchasers for the drugs we cover due to the way that drug manufacturers report their prices and Medicare's payment policies. Medicare should pay appropriately for all Medicare benefits, including the drugs we currently cover, and it is unacceptable that the current system results in Medicare paying excessive prices. We also need to pay appropriately for the services required to furnish these drugs. I appreciate your dedication and leadership on this issue, and I look forward to working with you and your colleagues to ensure that Medicare beneficiaries have access to the drugs they need and that Medicare pays competitive prices for these prescription drugs.

By law, Medicare does not pay for most outpatient prescription drugs. However, there are some specific exceptions where Medicare covers pharmaceuticals, such as drugs furnished incident to a physician's covered services, and in these cases, the law mandates that we pay physicians and other providers based on the lower of the billed charge or 95 percent of the drugs' average wholesale price (AWP). Numerous studies have indicated that the industry's reported wholesale prices, the data on which Medicare payments are based, are vastly higher than the amounts that drug manufacturers and wholesalers actually charge providers. That means Medicare beneficiaries, through their premiums and cost sharing, and U.S. taxpayers are spending far more than the "average" price that we believe the law intended them to pay. Some affected physicians and providers have suggested that they need these Medicare "drug profits" to cross subsidize what they believe are inadequate Medicare payments for services related to furnishing the drugs, such as the administration of chemotherapy for cancer. I believe we need to pay appropriately for both the drugs and the services related to furnishing the drugs.

Clearly, Medicare drug pricing is a complex issue. Over the years, numerous legislative efforts have failed to develop an effective alternative to AWP and ensure that Medicare and its beneficiaries do not pay more than they should for the limited number of prescription drugs that Medicare covers. We are committed to working with Congress on a bipartisan basis to ensure that Medicare pays accurately for all of its benefits. As we look to the future, particularly in the context of developing a Medicare drug benefit that does not make the same mistakes, I think it might be important to review previous efforts to reform the AWP payments so that together we can develop a workable solution.

#### MEDICARE'S LIMITED DRUG BENEFIT

The Centers for Medicare & Medicaid Services (CMS) pays most of the health care expenses of almost 40 million Medicare beneficiaries. If we were creating the Medicare program today, a prescription drug benefit certainly would be included. However, in 1965, prescription drugs played a less prominent role in health care, and the emphasis then was on ensuring access to inpatient hospital care in Medicare Part A and providing access to physicians in Medicare Part B. Today, Medicare beneficiaries rely on prescription drugs as an integral part of their health care. Although by law, Medicare does not generally cover over-the-counter or outpatient prescription drugs, currently Medicare does cover some drugs, including:

- Drugs that are not self-administered and furnished "incident to" a physician's service, such as prostate cancer drugs;
- Certain self-administered oral cancer and anti-nausea drugs;
- Certain drugs used as part of durable medical equipment or infusion devices, (e.g., the albuterol that is put into nebulizers, which are devices used by asthma patients);
- Immunosuppressive drugs, which are used following organ transplants;
- Erythropoietin (EPO), far and away the drug Medicare spends the most money on, is used primarily to treat anemia in end stage renal disease patients and in cancer patients; and
- Osteoporosis drugs furnished to certain beneficiaries by home health agencies.

These drugs are typically provided in the hospital outpatient setting, dialysis centers, or in the doctor's office, and are purchased directly by the physician or provider. Additionally, vaccines for diseases like influenza, pneumonia, and hepatitis are considered drugs, and are covered by Medicare.

By law, we generally pay for these drugs based on the actual charge or 95 percent of the AWP, whichever is lower. This adds up to more than \$5 billion a year for currently covered drugs, approximately 80 percent of which is paid for by the Medicare program. In general, Medicare beneficiaries must also share in the cost of pur-

chasing these drugs through their Part B premiums, and except for the flu and pneumonia vaccines, the \$100 Part B annual deductible, and a 20 percent coinsurance.

#### MEDICARE PAYMENT FOR CURRENTLY COVERED DRUGS

The AWP is intended to represent the average price at which wholesalers sell drugs to their customers, which include physicians and pharmacies. Traditionally, AWP has been based on prices reported by drug manufacturers and published in compendia such as the Red Book, which is published by Medical Economics Company, Inc. However, manufacturers and wholesalers increasingly give physicians and providers discounts that reduce the actual amount that the physician or provider actually pays for the drugs. These discounts are not reflected in the published price and reduce the amount providers actually pay to levels far below those prices published in the Red Book. Furthermore, use of the AWP, as reported by manufacturers to companies which compile such prices creates a situation where a manufacturer can, for certain drugs, increase the reported AWP and, in turn, offer physicians a deeper discount.

This Committee, CMS, the Department's Office of the Inspector General (IG), and others have long recognized the shortcomings of AWP as a way for Medicare to reimburse for drugs. The IG has published numerous reports showing that true market prices for the top drugs billed to the Medicare program by physicians, independent dialysis facilities, and durable medical equipment suppliers were actually significantly less than the AWP reported in the *Red Book* and like publications. As competitive discounts have become widespread, the AWP mechanism has resulted in increasing payment distortions. However, Medicare has continued to pay for these drugs based on the reported AWP amount. By offering physicians and providers deep discounts compared to the price they could bill Medicare, the drug manufacturers are able to use profit margins to manipulate physicians and providers to use their products for Medicare beneficiaries. It is simply unacceptable for Medicare to continue paying for drugs in a way that costs beneficiaries and the program far more than it should.

In the past, the Agency has attempted to remedy disparities between Medicare payments based on AWP and the amount actually paid competitively by physicians and providers. However, these efforts have not been successful. For example, in CMS/HCFA's June 1991 proposed physician fee schedule, the Agency proposed that payment be based on 85 percent of AWP. We also proposed that certain very high volume drugs be reimbursed at levels equal to the lesser of 85 percent of AWP or the physician's or provider's estimated acquisition cost. We received many comments, primarily from oncologists, indicating that this 85 percent standard was inappropriate. Most comments indicated that while many drugs could be purchased for less than 85 percent of AWP, other drugs were not discounted. Others suggested that while pharmacies and perhaps large practices could receive substantial discounts on their drug prices, individual physicians could not. As an alternative, beginning with 1992, a policy was established for Medicare to pay the AWP or the estimated acquisition cost, whichever was less.

Since the Estimated Acquisition Cost approach proved to be unworkable, subsequent legislation was proposed that would have required Medicare to pay physicians their actual acquisition cost for drugs. Under this proposal, physicians would tell Medicare what they paid for the drugs and be reimbursed that amount, rather than the Agency developing an estimate of acquisition costs and paying physicians based on that estimate. After considering this proposal, Congress adopted an alternative approach in the Balanced Budget Act of 1997 (BBA), setting Medicare's payment for drugs at the lesser of the billed charge or 95 percent of AWP. While this brought Medicare payments closer to the prices that physicians and providers pay for drugs, Medicare payments were still significantly greater than the competitive discounts obtained by physicians and the system still tied Medicare payments to the artificially inflated industry-reported list prices. In fact, in a December 1997 report, the IG found payments based on AWP to be substantially greater than the prices available to the physician community. As an alternative to actual acquisition costs, Congress considered proposals to pay all Medicare drugs at 83 percent of AWP, a compromise between 95 percent of the AWP and the average discount found by the IG.

In May 2000, the DOJ and the National Association of Medicaid Fraud Control Units made accurate market wholesale prices for 49 drugs covered by Medicaid available to State Medicaid programs and to First Data Bank, a drug price compendia owned by the Hearst Corporation. These wholesale prices, culled from wholesale catalogs circulated among the provider community, reflected the actual Average Wholesale Prices for these drugs far more accurately than the drug manufacturers'

AWP. Last year, HCFA sent this new information to Medicare carriers and instructed them to consider these alternative wholesale prices as another source of AWP data in determining their January 1, 2001 quarterly update for many of these drugs. However, due to concerns about Medicare payments related to the administration of the chemotherapy and clotting factor drugs, the Administration instructed our carriers not to use the data for those drugs at that time.

In December 2000, Congress enacted the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA), which established a moratorium on decreases in Medicare drug payments while the General Accounting Office (GAO) conducted a study of Medicare drug pricing and related payment issues. HCFA postponed Medicare carriers' use of the DOJ data until we could review the GAO report. We look forward to reviewing the GAO's findings and working with you to revise Medicare's drug payment policy. We must ensure that beneficiaries and Medicare pay appropriately for both the drugs that we cover and the services related to furnishing the drugs.

#### CONCLUSION

Medicare beneficiaries rely on prescription drugs, and the coinsurance they pay for covered drugs is tied directly to the prices that Medicare pays. We must find a competitive way to ensure that Medicare beneficiaries and taxpayers are no longer paying excessive prices for drugs that are far above the competitive discounts that are widely available today. We need to pay appropriately for all Medicare benefits, including the prescription drugs we cover and the services required to furnish those drugs. We look forward to reviewing the GAO report, and working with you Mr. Chairman, this Subcommittee, and the Congress to revise Medicare's payment policy for currently covered drugs. Thank you for the opportunity to discuss this important issue with you today, and I am happy to answer your questions.

Mr. GREENWOOD. Thank you, Mr. Scully. We appreciate your testimony and your presence and again your endurance in staying with us all this time.

Let me, first of all, comment on why the 85 percent of AWP obviously won't work. Because, as we've seen, some AWP's are actually straight; and particularly when there's no competition there's no incentive for the drug companies to falsify the AWP. So to reimburse 85 percent wouldn't be fair for those who are paying a hundred percent of the AWP, because the physicians would lose money every time. So clearly that won't work.

We do have five principles that my staff and I have worked out in terms of what we think the direction of the legislation that we hope to enact into law in the next month is, and I'd just like to tick these off for you and see if we have general conceptual agreement on how to proceed.

No. 1 is that any new drug reimbursement should not adversely impact Medicare patient access to quality health care. Would you like me to repeat that?

Mr. SCULLY. I'm sorry. I was trying to find your—

Mr. GREENWOOD. The question is, would you agree in concept with these five principles for legislation: Any new drug reimbursement should not adversely impact Medicare patient access to quality health care?

Mr. SCULLY. Sure. Absolutely.

Mr. GREENWOOD. That is a no-brainer.

Mr. SCULLY. That was an easy one. Thank you.

Mr. GREENWOOD. Medicare's reimbursement for coverage drugs should be closely linked to the prices that providers actually pay for the drugs.

Mr. SCULLY. I think that is the bottom line goal, yes.

Mr. GREENWOOD. Three, Medicare services and administration should be reimbursed according to their costs, exclusive of any reference to drug reimbursements?

Mr. SCULLY. The only caveat I'll put into that is, having been in the hospital business for years, costs—but, yeah, actual, real expenses, yes, because cost is what we paid for for years, and that is real life.

Mr. GREENWOOD. Understood.

Fourth, the impact of Medicare's drug reimbursement policies have—upon the making of clinical decisions should be eliminated or reduced to the greatest extent possible.

Mr. SCULLY. Yes. I think absolutely.

Mr. GREENWOOD. Okay. And, fifth, Medicare's reimbursement for treatments in related settings should be equalized to discourage migration between settings based upon relative levels of profit available to providers.

Mr. SCULLY. Yes.

Mr. GREENWOOD. Bottom line there is we don't want to drive these patients certainly back to a hospital setting which costs Medicare more and is sometimes a less pleasant experience for the patient.

Let me ask you this. These principles are not rocket science. This is a very manageable issue, as far as I'm concerned, based on my research here. The GAO report today gives us the foundation in terms of the expenses or costs for the oncologists. I hope we'll erase what has been an obstacle before, which is the legitimate concern raised by Members of Congress, frankly, because we do not have the data to forestall anything that might have some of these adverse effects on patients or providers.

If in fact we can put a legislative solution into some kind of an omnibus package that we sign into law—have signed into law, let us say sometime in October, do you have a sense from talking with your staff yet how long it might take CMS? How much time do you need to enact this so that we get a good system that works well, meets all of these objectives and begins to save the beneficiaries and Medicare the billions of dollars that we've talked about?

Mr. SCULLY. Well, clearly you can start paying different drug prices in AWP pretty quickly. The real issue is making—I think there is some legitimate argument that oncologists, as I mentioned, dialysis clinics—there are a variety of practice groups, at least an argument I've heard, on DME providers. The issue is that we put out our rates on January 1. Most of those rates are already in place. The systems are hard to change. The issue is from an equity point of view, and if there are providers that rely on inappropriately high AWP payments—

Mr. GREENWOOD. If I may, I should have included—incorporated that in my question. But if we give you the objective of coordinating in time this two-step process, move from AWP to a more cost-related—price-related reimbursement rate and reset the practice expense and the reimbursements for these specialties who are—specialists who will in fact lose revenue as a result of this change, how long would that take?

Mr. SCULLY. The quickest way we could rationally do it—again, I can tell you what my—all the people that have to do the actual

work, which a lot of people forget. There's actually lots of people in Baltimore here that have to actually do this. The quickest way you really do it is fiscal year 2003, for the fee schedules that come out in January of 2003, because that is really only the time you go back and recalibrate up the practice expenses and everything else.

It's possible—nobody is happy with this answer in CMS, I can tell you, but it's possible that if you directed us and you put money into the second half of 2002, that for the last two quarters of 2002, we could possibly—and I'm not even certain of this now—recalibrate some of the payments up.

We certainly can pay less on AWP, but if you're trying to find the balance, what I've heard from oncologists and others is, if you're going to cut the AWP, which we rely on, you need to fix the practice expense at the same time and in the same bill. I imagine they wouldn't be very happy to have the drug reimbursement cut at the same time the practice expenses don't go up. So pushing the envelope as much as it possibly can be—and I can tell you this is an extremely unpopular opinion with the staff at CMS—the fastest we could possibly do it is probably next July, and under normal circumstances, the fastest we could do it is January of 2003.

Mr. GREENWOOD. That is very helpful. I appreciate that.

My time has expired. The Chair recognizes the gentleman from Ohio, Mr. Brown, for 5 minutes.

Mr. BROWN. Thank you, Mr. Chairman.

Mr. Scully, nice to have you in front of the subcommittee.

You have the authority now to use an inherent reasonableness standard to reduce reimbursements for Medicare drugs which basically bear no resemblance to actual costs or actual cost plus. Do you have that story?

Mr. SCULLY. I think we do. I think the issue here is, as I mentioned, the agencies have a hard time getting around that. We actually sent out guidance of what we thought was an AWP—not me, but, as you know, Nancy-Ann DePerle and Secretary Shalala—about a year and a half ago to have our carriers interpret what was a low AWP, and there was quite an uproar about that, and the result of it was a legislative prohibition about changing it. So it's very debatable from a legal point of view as to whether we do have the authority. So if Congress doesn't act, we'll certainly look into it, but it would be far preferable to have legislative guidance.

Mr. BROWN. Wasn't there a GAO review and they said it was adequate? GAO did a review and said it was adequate?

Mr. SCULLY. A review of the practice expenses or the—

Mr. BROWN. Of the inherent reasonableness.

Mr. SCULLY. I think I read the report last night, and I think that—their view was we have an inherent reasonableness authority to interpret what the AWP is, and I believe he said in his testimony that it says average wholesale price in the statute. But as a former pretty bad lawyer, somebody who has had—been sued numerous times this fall, I would say that with the track record of having the government use the AWP for 30 years, I would have very little doubt that our authority to do that would be challenged. We certainly are willing to do it if it comes to that, but it would be much sounder I think if we get legislative guidance.

Mr. BROWN. Would it be appropriate first, Mr. Chairman, or Mr. Scanlon to address that, that the GAO did in fact find that. Correct?

Mr. SCANLON. We reported on the expedited inherent reasonableness authority that you gave to the agency in the Balanced Budget Act which allows for up to a 15 percent reduction, again, in an expedited fashion. Whether we have the ability to redefine AWP and define it any way we'd like is a somewhat dicey legal issue. We're happy to—believe me, we're very anxious as you are to fix this. I would say it would be certainly much more likely to succeed if we had additional legislative guidance.

Mr. BROWN. Could you submit a legal opinion for the record on that?

Mr. SCANLON. Sure.

Mr. BROWN. Let me shift gears for a second. Before that, I just—if in fact you can do that, using an inherent reasonableness standard to reduce reimbursements, I would hope that CMS could be more aggressive. I guess you have a pilot project in Texas and look to do more of that for competitive pricing in the months ahead.

All the talk about the solutions that have been bandied about in the prior panel and from opening statements and others, if Medicare changes the way that Congress pays for prescription drugs, obviously then changing the reimbursement rate for oncologists and saying that the practice expense payment system needs to be adjusted, what does that do—my understanding is the entire pool of practice expense payment needs to be budget neutral. Does that mean any increase in practice expenses for oncologists would then cause a reduction in practice expenses for other specialties?

Mr. SCULLY. Well, under current law it would or wouldn't change, and I personally would not recommend us doing that, because I don't think we should be taking funds from other practice expenses to fund oncology. I think the discussion that's been had in some quarters about legislation is that if you're going to change the AWP legislatively you will get significant baseline savings, and some of that could go back into just adding in a nonbudget neutral fashion back into the practice expense pot, which you can do legislatively to increase, where appropriate, some practice expenses in some areas without taking it from others.

But, clearly, without legislation, any practice expense change has to be budget neutral.

Mr. BROWN. So if we were to do that, do you have any suggestions on the amounts of—you, first of all, say we in a sense legislatively break the budget neutral concept of practice expense, at least for this particular case. What kind of money do you talk about in terms of the oncologists then versus what we've done?

Mr. SCULLY. Chairman Greenwood and I talked about this a little bit, and he—apparently in the GAO reports read last night, they suggested \$51 million. It's not always easy to get a quick back-of-the-envelope read from my staff, but I think that number is in the ballpark. It's close, somewhere in the 40—I mentioned to him that our back-of-the-envelope number was pretty close to that, in the \$45 to \$55 million range.

Mr. BROWN. What are you hearing from other physicians, other specialties about the practice expense issue?

Mr. SCULLY. You know, in fairness, I was one of the drafters of my first job and the first—one of my first jobs in the first Bush administration was passing RVRS in 1989, since I was primarily responsible for the administration's position back then.

One of the reasons I like it—

Mr. BROWN. A lot of complaints should be directed to you then.

Mr. SCULLY. Yeah. It's all my fault. They didn't like it much back then, but, in fairness, I think the system has worked reasonably well. If you look at all the other reimbursements over the last 15 years, nursing homes, hospitals, everything else has been an up-and-down roller coaster. Physician reimbursement has been relatively—as I'm sure the physicians on the committee might not agree, but I think generally even the AMA would tell you that, relative to other reimbursements in Medicare, it's been more predictable and more stable and the system has worked reasonably well.

The thing about practice expense is that basically we rely 98 percent of the time on the—what's called the RUC, which is essentially the committee through the physician groups to recommend what the practice expenses should be. So if the oncologists think they're underpaid, they have to come argue why it should come out of the oncologists versus the surgeons, versus the gastroenterologists, and they sit around a table every year and make recommendations, the vast majority of which we take. But it's a finite pot, and I think it works reasonably well.

So the issue here is—it's the physicians all sitting around the table with CMS saying who is underpaid and who is overpaid, and they're all arguing over a finite pot that you've authorized. And I think it works actually reasonably well. I mean, everybody is unhappy, but once everybody is unhappy that usually means it's working right.

Mr. BROWN. Thank you, Mr. Chairman.

Chairman TAUZIN. I thank my friend. The Chair recognized him so briefly for a round of questions.

Thanks for coming, Mr. Scully. Of course we appreciate you being here.

Let me ask you in regard to that finite pot. If we are going to work out a solution that establishes a responsible AWP, something more akin to the real cost of the drug, and it reduces the income to the oncologists significantly and the oncologist does have a claim that he is under-reimbursed for practice expenses, which you and I think GAO both have conceded is true, at least to some extent—you've identified it around \$50 million. If we simply say that we're going to permit the oncologist to have a larger share of that finite pool, does that ipso facto mean that other physicians, other service providers will lose reimbursement as a result?

Mr. SCULLY. If we were directed to do that administratively without new money in the pot, it would, but my hope would be that in the same—what I've heard from responsible oncologists, of which there are many, is that they agree that many of the things in the system are broken and in fact if we fixed in the same bill simultaneously AWP and adjusted their practice expenses, they don't think that is necessarily unfair. Now some may disagree with that.

Chairman TAUZIN. Provided we increased the pool to accommodate to whatever few reimbursements we ought to provide for those physicians. Is that correct?

Mr. SCULLY. Once again, in fairness, Mr. Chairman, I think—and I'd like to work with your staff on—I do think it's not oncologists who've made the most noise on this. I do think dialysis providers of a number of drugs and I think hemophilia agencies do. And, to a lesser degree, we ought to look at other providers and make sure they also are made whole.

Chairman TAUZIN. We've got to look at every single provider that may be losing income as a result of a change in AWP and examine whether or not in fact their practice is being properly reimbursed under the current system. Is that correct?

Mr. SCULLY. Yes.

Chairman TAUZIN. And we need to come up with a number that we need to add to the pool to make it fair, and there is a disagreement on that number, right? I mean, you and GAO have a number around 50—

Mr. SCULLY. Pretty close. I think we're pretty close.

Chairman TAUZIN. I've heard some extraordinary numbers coming from some of the care providers. So we're going to have to somehow provide some rationale for a proper number. Is that correct?

Mr. SCULLY. Yes, sir.

Chairman TAUZIN. Second, why don't you now use the average manufacturers' price and best price under the Medicaid rebate program in establishing an average wholesale—or average wholesale price? I think I know the answer why you don't, but tell me.

Mr. SCULLY. I believe it's statutory. That's another thing that I hate to say that I helped create at Andrews Air Force Base in—

Chairman TAUZIN. So if you're going to use it, we have to change the law?

Mr. SCULLY. If you wanted—the way it works is we do use average manufacturers' price, I believe, and my staff might correct me if I'm wrong, but the rebate—it comes up that the difference between the AWP that's charged and the average manufacturers' price is just a small piece of it. So you could, in fact, correct Medicaid law as well and arguably make it more appropriate.

Now, the two sides—just to give the other side, you probably hear from private insurance companies is there's no doubt what we're paying in Medicare in a big way and arguably in Medicaid in a smaller way, but when you put those two programs together and you squeeze the pot that's going to bounce back on the private insurers. So—to some degree.

Now, there's no question to some it's excessive margin. But if you take Medicare and Medicaid which are—at least in the hospital outpatient setting, 40 percent of that is usually Medicare. Maybe 12, 14 percent is Medicaid. Then you squeeze down on their reimbursement there, which we certainly need to do, you're going to have the insurers and others on the private payer side come back and say our drug prices just went up.

Now, again, I would very much doubt that is a wash. I think the margins on the Medicare side are extreme, to say the least.

Chairman TAUZIN. And you both tend to say that. We have at least some evidence coming in from the other side claiming that it's a wash. We're going to have to again get some sort of arbitration on that number to find out what it is.

Mr. SCULLY. I think generally the insurance plans are—you know, they have the flexibility to negotiate prices, and they generally can fend for themselves pretty well, but you will hear a push back from the other side.

Chairman TAUZIN. Let me ask you a very simple question that I think I know the answer to, but you might give us some insight on it. Why on earth do we have a system that requires a Medicare beneficiary to pay 20 percent as a copay of an artificial price? It can exceed the real cost of the drug to the physician. What would happen if the law would change or some provision were made, either administratively or by change of law, to require that the 20 percent copay would be 20 percent of the real price paid by the care provider for the drug? What is wrong with that?

Mr. SCULLY. Other than the budget spending, it sounds like a great idea, and I think—

Chairman TAUZIN. It would save American patients \$177 million that they're spending on excessive copays, because copays are based on fictitious numbers. I mean, when a patient has to pay 500 percent for this one drug I cited of the amount the doctor is having to pay for that drug as a copay, I mean, citizens look at that and say, you know, that's Alice in Wonderland. It's just crazy. Shouldn't the copay be based upon the real cost of the drug to the doctor, and what would it take to do that?

Mr. SCULLY. Well, that may be—that gets into the delicate difference, as I said. But we can probably figure out exactly what we should be paying the manufacturers and recoup it, much the way Medicaid does through a reconciliation.

The issue is, if you're trying not to squeeze, the physician is trying to buy it out in the market at the beginning of the year. Finding out what—the right number to charge the 20 percent copay against is one the tougher things to figure out.

Chairman TAUZIN. It is not hard to figure out. You simply have a provision that says you can't charge the doctor or physician as a co-pay more than 20 percent of the drug—

Mr. BROWN. Will you be able to do that administratively, the chairman's suggestion, simply so that the patient would pay the 20 percent of what the actual charge, what the doctor's actually charging for the drug? Could you do that?

Mr. SCULLY. Well, the closest thing we have right now, the ability to actually determine what the actual price paid is, is the average manufacturer's price which we have for the purposes of Medicaid the worst—

Chairman TAUZIN. Let me say it again. If the law said that the doctor can't charge the patient more than 20 percent of the actual cost, it is the health care provider's obligation then not to send a bill that is represented on 20 percent of some fictitious price, he's got to look at what he has actually paid and send a bill based on 20 percent of what he really paid for the drug. Otherwise he is in violation. That is pretty stiff, but what is wrong logically with that

if at the same time we are making the proper adjustments for practice reimbursement to the physician?

Mr. SCULLY. Nothing. It seems logical, and I think the question from Mr. Brown was can we do it now administratively and I don't think we can.

Chairman TAUZIN. Also doing it administratively without correcting the reimbursement on the fund is disjointed. I understand that. There is a \$177 million hit for health care providers. But the fairness of asking a Medicare patient to pay 20 percent of a price that is totally fictitious, way in excess of what the physician actually bought that drug for, seems to me to be absolutely insane. It contradicts what we did in the Medicare program, which was literally to provide a co-pay requirement on the patient that was supposed to be one-fifth of the actual cost and, because of this crazy system of average wholesale pricing, can run as high as 500 percent of the cost. And I mean not only is it unfair basically to think about that but think about it in terms of if you happen to be the wrong patient, you happen to need that drug that is 500 percent as opposed to another patient that is paying closer to the real 20 percent. There is an inequity in the requirements under the Medicare system depending upon how unlucky you are, what disease you have got, what drug you need to help you.

I would think that we should all look at expediting a cure for that particular problem. Perhaps we can do that sooner than later.

Mr. SCULLY. We would love it. We are totally with you. I think the best thing about this hearing was for the health care policy wonks in the world, many on your committee, this issue has been around about 10 years and I never heard this thorough a discussion on it, and usually what happens is somebody tries to cut a rate and somebody screams that patients are going to be hurt, which is frequently not the case, and we are legislatively prohibited from fixing it.

Chairman TAUZIN. You said the right thing, legislatively prohibited from fixing it, and that can't stand any longer. It is our obligation right here to fix it. We have allowed this to exist too long, as we thoroughly understand it, as we understand its pernicious effects upon the health care system, and particularly upon the very people it is designed to help, we have got to fix it, and if there are legislative impediments to your fixing it, we need to take them out of the way.

Thank you very much. I will recognize Mr. Ganske for 5 minutes.

Mr. GANSKE. Thank you, Mr. Chairman. I want to follow up on your line of questioning. It seems to me that the problem with instituting a limit on the co-pay to the actual cost without doing the rest is just what we have been talking about multiple times this morning; that is, that you are not taking into account the overhead involved with the administration, with the storage, with the ordering, with the time involved for personnel and things like that, and so I think that that issue of the co-pay is corrected when you actually have the inaccurate index of the cost, I mean of the drug, whether it's an AVP, or whatever letters you want to use.

Mr. Scully, I want to go to this issue of the AMP data. This is a quote from the IG report. "This option would require legislation to allow Medicare access to AMP data. Prior to this option being

implemented, it would be useful to clarify or refine certain definitions. We also believe that an initial intensive effort should be made to audit AMP data." We don't want to just substitute some letters. We need to have some accuracy. Do you have any idea of what the definitions that we would need to address to clarify and define what the IG is talking about in terms of AMP?

Mr. SCULLY. That is considerably lower and I think it generally works. It is confined to Medicaid by statute, and our Medicaid staff has access to what the Medicare staff does not. It is audited. If we use it for a broader chunk of the market and used it for Medicare as well as Medicaid, obviously incentives for people reporting their prices would—we'd have to probably audit more carefully, as the IG said, and be much more thorough in making sure the prices are accurate. But the idea of AMP, which is similar to an average sales price concept, is to actually find out what the manufacturer sells it to all customers in the country in any particular year and then come back and make it that that is the average price that we pay. I think the data is there now to make it work, and it is certainly the best measure to make it work.

The problem is if you go out to many areas of the country where physicians and oncologists may actually have to pay more for it, there may be places where somebody can't get access to that. That was the argument about paying 85 percent of AMP back in 1991. If a physician in Iowa, for instance, couldn't get access to the drug for that price, he might never get it. So some have suggested that just consensually what we would do is allow the companies charge whatever they want, but then at the end of the year come back and reconcile, similar to what Medicaid does now, and say you sold us a million units of the drug times whatever the average manufacturer's average sales price is, you owe us the difference. That way you keep access to the physician out there buying in the market while actually recovering from the manufacturer.

The problem with that, which is what I was trying to get to Mr. Brown, is then what do you do up front as far as charging 20 percent of what, the inflated AMP or the real end of the year price the government ends up paying, and that is difficult.

All things I think we can talk about fixing legislatively, but it is a complicated problem to make sure we don't overpay, but that we also don't shut off access to physicians who may not in some parts of the country be able to get access to the drugs. So it is a complicated problem. I think we can fix it, but I have only been looking at it intensively the last 2 or 3 days and I can't tell you all the answers yet.

Mr. GANSKE. Can this committee expect from the administration and from you and CMS some specific suggestions for instance on the, quote, clarification and refinement of certain definitions, unquote, that we would need to do legislatively if we were looking at going the AMP route?

Mr. SCULLY. Sure. Obviously we are hoping, and if we are only here for a month to spend a lot of time on legislative issues, we certainly have a lot of suggestions in this area. We have already spent a lot of time talking to committee staff.

Mr. GANSKE. We are dealing with 24 drugs; is that right?

Mr. SCULLY. I think the bulk of the 24 is about 90 percent.

Mr. GANSKE. It would seem to me that we ought to be able to get a handle through sampling of real invoices on 24 drugs, what the real average wholesale price, or the AMP, should be to address this.

Mr. SCULLY. Actually the companies that report AMP are required to tell us what their average price was to all their buyers in the course of the year in any category, and we audit that. So it should be a pretty accurate number. We just can't use it right now for Medicare.

Mr. GANSKE. How do you audit that?

Mr. SCULLY. I believe the IG—the Medicaid actually goes into the companies and audits——

Mr. GANSKE. It goes into the company books and then checks——

Mr. SCULLY. That is right. It is the OIG who actually does it for us.

Mr. GANSKE. And then checks back with the customers of those companies to see whether that in fact——

Mr. SCULLY. Yeah. The only potential flaw I have seen is that some drugs, once you put Medicare and Medicaid together, it is—you know, to figure out what the rest of the market is paying and piggyback on that. A few of these drugs, the market is mostly Medicare and Medicaid. So it is a little difficult to figure out the prices if the non-Medicaid/Medicare market is 10 percent. That is the only flaw I have seen so far in looking at it.

Mr. GANSKE. We both know it has been difficult to get accurate indices of practice expense. There has been a lot of controversy in those areas. If we are talking about changing this reimbursement, what will be the process to get an accurate assessment from these medical specialties that will be affected?

Mr. SCULLY. I believe, and again I hope somebody will jump in here if I am wrong, all the specialties already have the ability to put in their own surveys. The oncologists could have put in their own practice survey and did not. The data that we had on oncology combined their actual drug costs so close to their practice expense costs that we made the decision, which I believe GAO agreed with, that we couldn't use that data. So we used the average physician's practice expense. I think that was defensible because arguably the physicians are already, from what we have heard today, being over-compensated on the drug side; so using the average physicians practice expense is reasonable.

If you in fact reduce the AVP and you made the judgment that we should go back in and do a survey of oncology data or have them submit their own, we believe that would result in their practice expenses going up, but right now the practice expense component for oncologists is the actual average practice expense for all physicians because we don't use oncology specific data.

Mr. GANSKE. We have testimony today from Dr. Norton to the effect that the Medicare payment for services for administration may be one quarter what the actual costs are. Do you have a feeling for that?

Mr. SCULLY. I have not, to be honest with you, looked at that level of detail. Totally independent of each other, both the GAO and our staff looked at this number and came up with a remarkably close initial determination. So I am happy to go back and

spend time with the oncologists discussing it, I am sure I will if you are looking at legislation, but I have yet to find a physician group that was not unhappy with their practice expense allocation. I think that is the nature of the beast.

Mr. GANSKE. Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes the gentleman, Mr. Norwood, for 5 minutes.

Mr. NORWOOD. I thank the chairman and I only have one question. I am curious to see what Mr. Scully has to say. You implied earlier there seems to have been a problem at least as far as 10 years back, that HCFA has been concerned and has raised questions about this for a long time, however generally when you raised questions very loud and stuck your head up very far, Congress pounced on you. Is that where we have been?

Mr. SCULLY. That is fair, but sometimes in fairness it is Congress, sometimes it is, you know, groups coming in and screaming within your own administration, whether it is—Gail Walinsky was the first person to get involved in this in 1991 and I was in the White House then, and I remember not knowing very much about it but I remember we got a lot of heat for it. I think the level of understanding and interest this year is an all-time high and that is positive. I think generally whether it is Congress or just people complaining about it, when you have talk about cutting, the groups that are affected are always upset, and generally they are upset because in the past the issue has generally been lowering reimbursements without being sensitive to the fact that maybe there is an unfortunate—but reality is cautious. As I mentioned, I know for ESRD clinics, they argue that their rates are too low as well and that they rely on AVP transfers and cost shifts. Generally the answer in the past has been cut the rates and don't be sensitive to the other side, which does not seem to be the case this year.

Mr. NORWOOD. My question, Mr. Scully, though, is since this has been a problem for a long time, I am a little bit surprised that why would not CMS or GAO or somebody be coming to this hearing today with a solution?

Mr. SCULLY. It is not an easy solution. I spent 4 hours the other day with probably 10 people at CMS that have worked on this for the longest time and went around with the options I put in front of you today briefly, and I am not sure we have a consensus in our agency about what is right. We are going to have to pick one. I think it will be a hybrid of a bunch of these, but I am not sure that you could find a consensus solution anywhere. I would be happy to sit down with the committee and give you my opinions.

Mr. NORWOOD. I was struck by the different options that you sort of threw at us pretty quickly, and I guess is this not solvable?

Mr. SCULLY. I think it is very solvable. I think there are shortcomings to every solution and some benefits to every solution, and some people are not troubled by just saying let us pay the Federal Supply Schedule. I don't think that that—which the VA pays, which the Coast Guard and other agencies pay. I think that probably causes significant access problems for some physicians in some places. So there are pros and cons to every option and, if you would like, I would be happy to share my staff paper on the pros and cons with you.

Mr. NORWOOD. I think my feeling is this, the Energy and Commerce Committee is going to do something about this one which way or the other and it certainly should be and is our responsibility, but I also think it is the responsibility of the Federal agency to also come up with a solution. It doesn't necessarily mean we will adopt that. It doesn't mean that that will be the final solution. But I think you need to lead your organization to the plate, get up to bat, let us hear what you want to do. And at the same time our chairman, all of them along the line are going to be doing the same thing. But I am not sure I feel like we, the members of this committee have—should have had the experience dealing with this problem for 10 years at the same level as your agency has had experience dealing with this problem, and I am suggesting that you have some responsibility in my mind to not give us a dart board and hope we hit the right one. Come in here and say what you want to do.

Mr. SCULLY. Mr. Norwood, I almost have never been accused of not having strong opinions about things for better or worse. The problem is that we are legislatively prohibited at least until today from considering this. So there is not an administration position. As I have—

Mr. NORWOOD. Are you prohibited from coming up with a solution?

Mr. SCULLY. No. But the fact is we have an administration with a White House and the Secretary—I have talked to the Secretary a little bit about it. I am not sure that the White House is aware of this. I can't state the administration's position publicly today. I have opinions. I will talk in the next week or so with people in the administration, and I have no doubt we will have a strongly held administration position. I am just not in a position today to go any further than I have.

Mr. NORWOOD. I didn't expect today for you to come up with a solution. I expected for you to turn to some of that staff that has been over there over the last 10 years and I presume are working on this. At some point in time the agency itself should make a recommendation as to how they think we would best solve this problem and hopefully this committee and the subcommittees and full committee will go along with that, maybe alter that, maybe change that. But you need to have a position.

Mr. SCULLY. I hope we can come up with a joint position with the committee, and we will give you lots of technical input, and whatever the committee decides I have a feeling will be the administration's position as well and we will hopefully do it together aggressively and on a bipartisan basis.

Mr. NORWOOD. Thank you, Mr. Chairman.

Mr. GREENWOOD. The time for the gentleman has expired. Let me comment that in fairness to everyone, we have all been on hold until the GAO study came out, which has been released today, and we now feel that we have a solid footing upon which to build our solution. The wholesale acquisition costs will almost certainly be the basis for the new reimbursement rates, will take care of the oncologists and others based on the data that we have now, and I think we will be prepared to work with CMS over the next couple

of weeks and have a firm detailed legislative product in short order.

Mr. Scully, thank you for your excellent testimony. Thank you for your patience and you are excused. Look forward to working with you.

I call now the third and final panel: Dr. Larry Norton, President of the American Society of Clinical Oncologists; Mr. Kevin Martyn, Executive Director of Care for Life; Mr. Thomas Connaughton, President of American Association of Homecare; and Dr. Ezekiel Emanuel, Chief, Clinical Bioethics Department, Warren G. National Magnuson Clinical Center, National Institutes of Health. Welcome. We thank you for your patience in waiting all morning and all afternoon to testify, but we are glad to have you with us.

As you probably heard me say to the previous witnesses, this is a joint committee hearing between the Health Subcommittee as well as the Oversight and Investigation Subcommittee, and when the Oversight and Investigation Subcommittee is involved, we take testimony under oath. Do any of you object to providing your testimony under oath?

Seeing no such objection, I would inform you that you are entitled under the rules of this committee and under the rules of the House to be represented by counsel. Do any of you desire to be represented by counsel? Seeing no such desire, if you will rise I will give you the oath.

[Witnesses Sworn.]

Mr. GREENWOOD. Thank you. You are each under oath now, and we will begin with you, Dr. Norton. You are recognized for 5 minutes for your testimony. Make sure your button is——

Dr. NORTON. Am I on?

Mr. GREENWOOD. Yes.

**TESTIMONY OF LARRY NORTON, PRESIDENT, AMERICAN SOCIETY OF CLINICAL ONCOLOGISTS; KEVIN MARTYN, EXECUTIVE DIRECTOR, CARE FOR LIFE; THOMAS A. CONNAUGHTON, PRESIDENT, AMERICAN ASSOCIATION OF HOMECARE; JOANN LAMPHERE, LEWIN GROUP; AND EZEKIEL EMANUEL, CHIEF, CLINICAL BIOETHICS DEPARTMENT, WARREN G. MAGNUSON CLINICAL CENTER, NATIONAL INSTITUTES OF HEALTH**

Mr. NORTON. Hi, I am Larry Norton. Pleasure to be here. I am a physician, an oncologist, and this year I am President of the American Society of Clinical Oncology. I am also a New Yorker. So I don't have to belabor this. It has been a really rough couple of weeks, but I am delighted that you are having this hearing at this time because this is a topic of great urgency and importance to cancer doctors and cancer therapists in the United States.

My organization represents cancer therapists, physicians, nurses, patient advocates, and others who take care of people with cancer and also people doing clinical research. I currently am also the head of Medical Oncology, called the Division of Solid Tumor Oncology, at Memorial Sloan-Kettering Cancer Center in New York. I have dedicated my life almost 30 years to cancer treatments, largely chemotherapy treatments and largely for breast cancer, and it is of critical importance to me and my colleagues that the thera-

pies that we develop that have been improving the life-span, cure rates, and the quality of life for our patients, that this can actually be delivered to our patients. So this is an issue of really critical importance to us.

We agree that the system has to be fixed. We think that the payments for the drugs have to be aligned more closely to the actual costs, but we also think that the payments for the services that are rendered in the administration of these therapies have to be made more realistic, and we think this has to be done very carefully, has to be done jointly, or else we see the possibility of severe disruption to the care of our Medicare patients, and for this reason I underscore the urgency of this particular activity.

We have made really significant progress in cancer therapy over the years. Many therapies that developed initially in the inpatient setting can now be given in the outpatient setting safely, the advances in treatment of nausea, advances in treatment of low blood cell counts, and many other improvements as well as the therapies themselves that have made such a difference. Therapies that used to require inpatient administration not that long ago can now be given—complex skill requiring therapies can now be given routinely in doctors' offices and this is more than just a convenience. This is an essential contributor to the quality of life as well as the length of life for our patients. We want to be sure whatever happens, whatever you decide to do and however you go about this, that the net result must be that doctors will be able to give chemotherapy to their patients in their offices. We calculate that about 70 percent of chemotherapy treatments are given in doctors' offices right now. If the payments, the total payments, for these therapies are not adequate, doctors will not be able to afford to do it. Some people said then they will refer them to hospitals or cancer centers. Cancer centers could be very far away from the patient in many parts of the country, and I don't know any cancer center that can handle a large influx of patients in this particular setting, certainly not my own.

I am in charge of the Outpatient Breast Center of Memorial Sloan-Kettering Cancer Center and if we had a sudden influx of cancer patients with—breast cancer patients in the community for us to treat, we just couldn't handle it. So I don't think that is really a solution. Therefore, whatever we do if we don't do it carefully, we could see a real massive disruption in the system.

So much of the discussion today is concerned with reimbursement for the drugs that are administered. We think the system does need to be fixed. There is no question about that, but I want to emphasize there has to be a simultaneous change in the reimbursement for the physician administering the therapy. Right now there is a gross underpayment, as everybody has acknowledged, and that the payments for drugs have to some degree compensated for that.

If we don't reform the whole system at the same time, things are going to get thrown out of whack. It is like a car with a bad axle and a bad tire rim. You fix one. If you don't fix the other, you can't drive the car. I think that's exactly the situation that we find ourselves in. Medicare has determined this and I haven't heard anybody say this is not the case.

I have a quote here that says Medicare payments for services related to provision of chemotherapy drugs are inadequate. We agree with this assessment. Actually our own calculations are that Medicare now pays for less than a quarter of the actual costs to the doctor in administering principal chemotherapy treatments. We think that part of this is the way that the—the methodology for calculating the payment amounts for services that do cost the doctor a lot but not directly furnished by the patient. In 1998, when Medicare adopted this particular methodology, it called its approach an interim approach, but it still hasn't been revised.

We also feel there has to be a new type of Medicare payment for services that are directly related to administration of chemotherapy, directly related but right now not covered by any explicit reimbursement. There are many services that oncologists and their staff provide that are absolutely essential for taking care of these patients, such as social work, such as nutritional counseling, such as psychological support, and these are not really being covered. A big difference between oncology and the specialties is in other specialties an occasional patient has this requirement, for the oncologist essentially all the patients, and this has to be provided as an intrinsic part of the procedure.

We believe that the costs of the chemotherapy administration has to be covered, but if it's just covered, then there is not going to be sufficient funds to provide these other critical services, and this has to be taken into account.

Now, concerning the payment for the drugs themselves, we agree with pretty much everything that's been said. The AWP really overstates by varying amounts the amount, and clearly this is a big problem. We think this is not right. Mr. Chairman, you use the word "outrageous," and I think it is a well chosen word. We actually have—we have proposals on the table. We have proposed a solution. It is in the form a white paper, and I would like to request that it be included in the record.

Mr. GREENWOOD. The document will be included in the record.

Mr. NORTON. Thank you. And in that we talk about the surveys of the drug sellers to determine market prices or a correction in the actual published prices, and that's really what should be used to determine the reimbursement. But fundamentally we believe that if the cost is not covered, it's going to be impossible for the doctors to administer the therapy. Our job is to take the best possible care of our patients with cancer. It's a very hard job. I want to emphasize that. It's not just the intellectual challenges. The field is changing all the time. It's the psychological challenges, the emotional challenges, the spiritual challenges and I've got to tell you the hours are just unbelievable.

We want to provide the very best care for our patients. We think that we need to have accurate reimbursements so we can do it financially. Anything that we do that is going to throw the system out of whack is going to hurt us from doing that. We are totally dedicated to quality cancer care and we want to work with Congress to make sure that the care we're now administering is provided at the highest possible quality level.

Thank you very much.

[The prepared statement of Larry Norton follows:]

PREPARED STATEMENT OF LARRY NORTON, PRESIDENT, AMERICAN SOCIETY OF  
CLINICAL ONCOLOGY

My name is Larry Norton, President of the American Society of Clinical Oncology (ASCO). ASCO is the national organization representing physicians who specialize in clinical research and the treatment of cancer. ASCO has over 17,000 members, including nonphysician healthcare professionals and cancer specialists located abroad.

I appreciate the opportunity to appear before the Committee today to present ASCO's views on the important subject of Medicare payment for the drugs and related services furnished in outpatient cancer treatment. ASCO agrees that Medicare payments for drugs and related services should be restructured to more closely align the payment amounts with the cost of providing cancer care. Payments for drugs should be reduced while payments for the related services should be increased. It is imperative that this be done carefully, however, to insure that delivery of treatment to Medicare beneficiaries is not disrupted.

NEED TO PRESERVE OUTPATIENT CHEMOTHERAPY

I am Head of the Division of Solid Tumor Oncology at Memorial Sloan-Kettering Cancer Center in New York. As a specialist in the treatment of breast cancer, I am very familiar with chemotherapy and its importance in cancer treatment. Any reform of the Medicare payment system for chemotherapy must insure that cancer patients can continue to receive what they need to fight their disease. Chemotherapy is central to modern cancer treatment and is likely to be even more important in the coming years. Chemotherapy treatment was once considered far worse than the disease, requiring extensive hospital stays. Now, with better drugs to control side effects, patients can receive treatments in outpatient settings most convenient for them—and for their families. This is usually in physician offices.

In restructuring the Medicare payment system for chemotherapy, the net result must be aggregate payment amounts that enable physicians to continue offering office-based chemotherapy. It has been estimated that 70% or more of chemotherapy treatments are furnished in physician offices. If Medicare payments are not adequate to cover the costs of this service, physicians will be forced to have chemotherapy delivered in some other setting. It is far from clear, however, whether hospital outpatient departments have the capacity or the resources to handle a large inflow of chemotherapy patients. Any significant reduction in office-based chemotherapy could therefore result in a massive disruption in the care of Medicare patients with cancer.

PAYMENTS FOR DRUG-RELATED SERVICES

As I stated above, ASCO supports a reduction in the Medicare payments for drugs. Before discussing that aspect, however, I want to speak first about the simultaneous change that must be made to insure that Medicare cancer patients will still be able to obtain chemotherapy treatment after the drug payments have been reduced. Under the current reimbursement system, the payments for drugs compensate for the underpayment or lack of payment for the related services, and all parts of the system must therefore be reformed at the same time.

In the 1970s, there were few drug treatments available for cancer and, as I mentioned earlier, those that were available were generally administered to hospital inpatients. The few types of chemotherapy that were first furnished in the office setting were relatively simple, but they established the basis for the low Medicare payment levels for chemotherapy administration services that continue to exist today. There has been no major revision, even though the complexity of chemotherapy furnished in the outpatient setting has increased enormously. This problem was noted by Congress as early as 1987, when the Omnibus Budget and Reconciliation Act required the Department of Health and Human Services to conduct a study of the costs of furnishing chemotherapy in the office and assess whether payments are adequate. Unfortunately, this study was never conducted.

Last year, however, the Health Care Financing Administration, now the Centers for Medicare & Medicaid Services (CMS), reviewed the matter and wrote Congress that "Medicare payments for services related to the provision of chemotherapy drugs...are inadequate."

The inadequacy of the Medicare payment amounts is illustrated by the costs of one of the principal services. Under the physician fee schedule, the current Medicare payment level for the first hour of a chemotherapy infusion (CPT 96410) averages about \$62. The cost of the supplies and equipment used in this procedure are estimated to be about \$29, based on the 1994-95 prices used by CMS for these esti-

mates. The salary and benefits of the oncology certified nurses who furnish chemotherapy are currently estimated by CMS to average about \$35 an hour, and the total nurse time involved in furnishing an hour of infusion is estimated at about two hours. Among other elements, this work includes reviewing the patient's medical history, verifying the drug orders, preparing the drug, educating the patient, assembling the necessary supplies, administering the drug, documenting the procedure, and follow-up phone calls.

Thus, the costs of the supplies, equipment, and nurse time for an infusion by themselves significantly exceed the Medicare payment amount. Moreover, there is nothing in the Medicare payment to cover the other costs of the office, including the administrative staff and the overhead, which CMS, using American Medical Association data, estimates to be about two-thirds of a physician's costs. The Medicare payment amount for chemotherapy services are far less than the costs incurred to furnish the services. ASCO estimates that Medicare pays less than one-fourth of the total costs of the principal chemotherapy procedures.

ASCO believes that this underpayment results at least in part because of the way in which the methodology for the Medicare physician fee schedule sets payment amounts for services that may represent significant expense to a practice but are not directly furnished by the physician. Chemotherapy is one example. At the time CMS adopted this methodology in 1998, it characterized its approach as "interim" but the methodology has not yet been revised.

ASCO believes that the payment amounts for services of this kind—those that do not have a physician work component—should be based on information about the costs of providing those services, and not on the current "top-down" methodology that is used in general to set payment amounts. Although it would be desirable to collect new cost data, any restructuring in the near future must depend on information that currently exists or can be promptly developed. Consequently, ASCO recommends use of the data on costs that was initially developed by the Clinical Practice Expert Panels and has subsequently undergone review in the American Medical Association refinement process and analysis by CMS. Medicare should pay the full direct and indirect costs of chemotherapy services as estimated in that process.

There should also be a new type of Medicare payment for services that are related to chemotherapy but are not part of the chemotherapy procedure itself. Oncologists and their professional staffs typically furnish a variety of services to cancer patients for which there is no explicit reimbursement. These services include the extensive support that seriously ill cancer patients frequently require, including social worker services, psychosocial services, and nutrition counseling. Social worker services encompass a variety of services intended to help patients carry out their therapy, such as help with insurance, arranging transportation to treatment, and filling prescriptions. Psychosocial support includes services such as counseling patients on their activities of daily living, support groups that meet in the physician's office, and grief counseling. In addition, physicians treating cancer patients perform an extraordinarily high amount of work outside the patient's presence, including family counseling, telephone calls, arranging for entry into clinical trials, and so forth. While other types of physician specialists may provide such services to occasional patients, oncologists and their staffs typically provide these services to the bulk of their entire patient load. If the Medicare payments for the drugs and drug administration are aligned closely with their costs, there will not be sufficient funds available to continue these services, which are so important to the seriously ill cancer patient population. Medicare patients need to continue to receive these services to deal with their disease, and the services should not be cut off to save money.

#### PAYMENTS FOR DRUGS

Finally, let me turn to the Medicare payments for the drugs themselves. The current Medicare payment amount for covered drugs is based on 95% of published average wholesale price (AWP). As is widely known, published AWP overstates, by a varying amount, the prices at which drugs can actually be purchased. This circumstance does not necessarily make AWP useless, however, and AWP is widely used by public and private insurance programs in their reimbursement methods for drugs that are dispensed by pharmacies or administered in physician offices.

In recent years, the difference between AWP and actual prices for some drugs has become very large. This situation typically occurs for multiple-source drugs or drugs with close competitors, where competition forces down the actual price even though the list price, on which AWP is based, remains high. The large discrepancy between price and reimbursement amount for some drugs is not an appropriate situation.

As part of restructuring the Medicare payment system, ASCO recommends one of two approaches to revising the payments for drugs. First, Medicare could deter-

mine the market prices of each drug. Instead of using AWP, the law could require drug wholesalers to report to a Medicare contractor the prices at which they sold each Medicare-covered drug, considering all discounts, and the quantity sold at that price. The contractor could then compile those reports into a picture of the range of market prices for each drug and set a Medicare payment level accordingly.

If this market approach is adopted, ASCO believes that a number of features should be included to insure that the survey results in an appropriate payment level:

- The price reports should be frequent so that they reflect changing market conditions. ASCO recommends that the wholesalers submit reports every month and that the contractor process the data promptly so that it can be used for reimbursement purposes in the second following month. For example, prices of drugs sold in January would be used to set the payment amounts for March.
- Since there will be a variation in the prices, the Medicare payment level for each drug should be set at an amount that will cover the prices actually paid by the vast majority of physicians. ASCO recommends the 95th percentile. Prices actually paid may vary greatly because physicians in larger groups are able to negotiate lower prices based on their volume purchases. It would be extremely unfair to pay based on the median price or some similar price because that would systematically discriminate against physicians who are unable to negotiate lower prices. Oncologists who are routinely reimbursed less than what they pay for a drug would be unable to continue furnishing drugs to their patients.
- The payment methodology should be flexible enough to take known manufacturer price increases into account immediately. For example, if data on wholesale prices is collected during January for use in March, but the manufacturer raises the price of a drug by 5% on February 1, that should be taken into account in setting the March payment amounts.
- There should be an add-on amount to reflect certain costs associated with use of the drug. These include costs such as spillage, wastage, the opportunity cost of the capital tied up in drug inventory, procurement and storage costs, and unpaid patient coinsurance (bad debt). Although Medicare Part B does not ordinarily cover bad debt, bad debt here represents an out-of-pocket loss to the physician and should be treated specially. The various components of these extra costs are difficult to estimate, so ASCO recommends a flat 10% add-on to cover them.
- Sometimes physicians will encounter especially high prices for drugs, such as if they have to purchase a drug from a pharmacy in an emergency. The system should always allow a physician to be reimbursed for the actual acquisition cost by submitting documentation as to the purchase price.
- In states that impose a sales or gross receipts tax on physician-administered drugs, Medicare should also cover that amount so as to keep the physician financially whole.

An alternative approach to using a survey of market prices would be to make the published prices used by Medicare more accurate. The main concern expressed about the published prices has been the particularly large differences between the published prices and actual prices for some drugs. The law could be changed to require manufacturers to submit accurate prices to the publishers. This approach would have the advantage of not requiring a government contractor to compile data.

ASCO could support either of these approaches and we would be happy to work with Congress to develop the details of an appropriate methodology. Our concern is only that the resulting Medicare payment must be adequate to cover the full costs incurred by oncologists. Oncologists pay varying amounts for drugs, with large practices and entities able to obtain volume discounts not available to everyone. The methodology adopted must be adequate to insure that all oncology practices, regardless of size, obtain full reimbursement of all their drug-related costs.

#### HOSPITAL OUTPATIENT DEPARTMENTS

The Medicare statute ties payments under the hospital outpatient prospective payment system to AWP by paying for drugs used in cancer therapy based on 95% of AWP for a two to three year transitional period. As the payment methodology for drugs furnished in physician offices is revised, it is important that possible effects on payments for services in hospital outpatient departments be kept in mind. Hospital outpatient departments are an essential part of the delivery system for cancer care, and Medicare payments must be adequate to support their continued operation.

## CONCLUSION

In summary, ASCO supports restructuring Medicare payments for chemotherapy related services by reducing the payments for drugs and appropriately increasing the payments for related services. It is essential that the cumulative payments after this restructuring fully cover the costs of the items and services that oncologists furnish to cancer patients. If their costs are not covered, oncologists will be unable to continue furnishing chemotherapy in their offices, and the result could be extreme disruption of the cancer care delivery system.

Oncologists have dedicated their professional lives to treating patients with cancer, and our only objective here is to insure that our patients can continue to receive the therapy and services that they need in the setting that is most convenient and accessible. We believe that Medicare payments can be restructured without adverse consequences if our recommendations are adopted, and we look forward to continued work with the Congress toward that end.

Mr. GREENWOOD. Thank you very much, Dr. Norton. We appreciate your testimony. And now, Mr. Martyn, you are recognized for 5 minutes.

## TESTIMONY OF KEVIN MARTYN

Mr. MARTYN. Thank you, Mr. Chairman and members of the committee, for allowing me the opportunity to testify today. This hearing addresses a subject that has a potential to impact directly the quality of care that our patients receive, and I would ask that the prepared testimony that I have submitted be included for the record.

I am the Executive Director of Care for Life, which is a pharmacy and home health care provider. We provide blood clotting factor products and related services and support the persons diagnosed with hemophilia who self-infuse at home. The ability of our patients to treat their conditions by self-infusing at home instead of being treated in a hospital emergency room or treatment center allows individuals suffering from this condition to lead more normal, healthy and productive lives. We believe that home infusion also saves the government money.

Mr. Chairman, as a health care provider who has served the hemophilia community for many years, I very much appreciate this committee's concerns over the high cost of medications and providing care. I am aware that there has been considerable criticism for paying providers based on the average wholesale price, and I would agree that the AWP may not be the right mechanism for all parts of the Medicare program.

Having said that, Care for Life experienced firsthand last year what happened when AWP was reduced without adequate consideration for the impact on patient care. When AWP was suddenly lowered for blood clotting products, my company faced the difficult task of telling some patients that we could no longer provide care. We delayed this decision in every case for several months while operating at a loss, but as a business we cannot do that for long. Fortunately, in all but a handful of cases the State Medicaid directors decided to switch back to the previous accepted AWP levels or made modifications to their reimbursement level accordingly, and we were able to continue to provide care.

At least with respect to disease that we treat, the current payment mechanism has resulted in good care at a fair price. I would like to describe briefly how we arrived at this system, the system that at least for hemophilia works quite well.

Mr. Chairman, many years ago the primary way for hemophiliacs to receive care was to go to a hospital emergency room. There the doctor would examine them and continue to infuse and to notify the patient that they were having a bleeding episode, and of course in this diseased state many patients are aware previous to that of that situation. They would then be admitted, given an IV, or infusion, and then released.

Eventually policymakers, the health care industry, and the hemophilia community realized it would be just as effective medically to encourage a shift to self-infusion at home and that doing so would in many cases be better for patients. Home infusion is better because patients begin to infuse sooner, which stops the bleeding faster, thereby decreasing likelihood of greater damage. In addition, Medicare and Medicaid pay dramatically less than if a patient had to go to the hospital for treatment.

The idea worked and today Medicare and Medicaid enjoy very significant cost savings from home infusion. For example, according to a study published in the *Journal of Care Management* in June 1998, treating a minor bleeding incident at home cost \$4,400 less than treating the same incident at the hospital. If only one-third of the hemophilia population experiences 10 minor bleeds for which they are needlessly required to visit the emergency room for treatment, the additional cost would be upward of \$44,000 per person for minor incidents per annum. Multiplying that by 8,000, roughly one-third of the hemophilia population, that total cost of government could be as high as an additional \$352 million annually. For severe hemophiliacs the additional cost of emergency room treatment would be much higher, more than \$100,000 per year. These additional costs do not include those costs associated with treating the increased physical injuries hemophiliacs suffer from the delay involved in having to make a trip to the emergency room.

In addition to the health benefits, self-infusion at home reduces administrative cost. For the service we provide the Federal Medicare program only makes one payment under Part B. With the reimbursement based on AWP, Care for Life performs all the services associated with providing the clotting factor. These services include having pharmacists on staff to dispense and track drug interactions, nurses, administrative personnel, shipping, storage, training, supplies, and the cost of advancing the money used for purchasing the clotting factor. Care for Life, like many of the providers upon which Medicare relies, is a for-profit enterprise. Just like any other business we must make a reasonable profit margin or investors will put their money elsewhere. After taxes we make roughly 7 percent, which I believe is a reasonable return.

If the reimbursement mechanism were changed so that the reimbursement was substantially decreased, providers like Care for Life would be forced to send patients back to the hospital. That in turn would ultimately lead to increased costs to the Medicare and Medicaid programs and the decrease in quality of care received by individuals with hemophilia. It is an outcome that I am confident this committee will work to avoid.

Again, I thank you for holding this hearing and for giving me the opportunity to testify. I share in your concerns, and I applaud your

efforts to develop a reasonable approach to Medicare reimbursement, and I will welcome any questions you might have.

[The prepared statement of Kevin Martyn follows:]

PREPARED STATEMENT OF KEVIN MARTYN, PRESIDENT, CARE FOR LIFE

Chairman Bilirakis, Chairman Greenwood, Members of the Committee, good morning. My name is Kevin Martyn. I would like to thank you for the opportunity to testify today. This hearing addresses a subject that has the potential to impact directly the quality of care that our patients receive. I would ask that the prepared testimony that I have submitted be included in the record.

I am the President of Care For Life. Care For Life is a pharmacy and home health care provider. We provide blood clotting factor products and all related services and support to persons with hemophilia who self-infuse at home. The ability of patients to treat their condition by self-infusing at home—instead of being treated in a hospital emergency room or treatment center—allows individuals suffering from this condition to lead more normal, healthy, and productive lives. Home infusion also saves the government money.

Mr. Chairman, as a health care provider who has served the hemophilia community for many years, I very much appreciate this Committee's concerns over the high cost of providing care. I am aware that there has been considerable criticism of paying providers based on the average wholesale price, or AWP, and I would agree that AWP may not be the right mechanism for all parts of the Medicare program. Having said that, Care For Life experienced first hand last year what happened when AWP was reduced without adequate consideration for the impact on patient care. When AWP was suddenly lowered for blood clotting products, my company faced the difficult task of telling some patients that we could no longer provide care. We delayed this decision in every case by several months by operating at a loss. But as a business we could not do that for long. Fortunately, in all but a handful of cases the state Medicaid directors decided to switch back to the old AWP levels, and we were able to continue to provide care. At least with respect to the disease that we treat, the current payment mechanism has resulted in good care at a fair price. I would like to describe very briefly how we arrived at this system—a system that, at least for hemophilia, works quite well.

Mr. Chairman, many years ago the primary way that hemophiliacs received care when they were having a bleeding episode was to go to a hospital emergency room. There, a doctor would examine them and tell them what they already knew: they were having a bleeding episode and needed an infusion of clotting factor to stop the bleed. The patient would be admitted, hooked up to an IV, given an infusion, then released. Eventually, policymakers, the health care industry, and the hemophilia community realized that it would be just as effective medically to encourage a shift to self-infusion at home, and that doing so would in many cases be better for patients. Home infusion is better because patients begin to infuse sooner, which stops the bleeding faster, thereby decreasing the likelihood of greater damage. In addition, Medicare and Medicaid pay dramatically less than if the patient had to go to the hospital for treatment.

The idea worked, and today Medicare and Medicaid enjoy very significant cost-savings from home infusion. For example, according to a study published in the *Journal of Care Management* in June of 1998, the cost to the government of treating a minor bleeding episode in an adult male who self-infuses at home is \$1,186.

Alternatively, if that patient had to make an emergency room visit to get treatment—for the same minor bleeding episode—the cost to the government would be \$5,620. That is a difference of more than \$4,400 per incident, again, based on a *minor* bleeding episode.

Light to moderate hemophiliacs may bleed around 12 times per year. Those with severe hemophilia may experience a bleed 52 times per year. The Centers for Disease Control and the national organizations representing the hemophilia community estimate there are 17,000 to 30,000 hemophiliacs in the U.S. The reported numbers vary because not all hemophiliacs seek treatment at treatment centers that report to the CDC.

Accordingly, if only one third (approximately 8,000) of the hemophilia population experiences 10 minor bleeds for which they are needlessly required to visit the emergency room for treatment, the additional cost to the government would be \$44,000 per person for minor incidents in that year. The total additional cost to the government would be \$352,000,000 annually.

For severe hemophiliacs, the additional cost of emergency room treatment would be much higher, easily more than \$100,000 annually per patient. These additional

costs do not begin to address the increased physical injury hemophiliacs suffer from the delay involved in having to make a trip to the emergency room to get treatment or the additional costs involved in treating those increased injuries suffered as a result of the delay in receiving infusion treatments.

In addition to the health benefits, self-infusion at home reduces administrative costs. With respect to providing clotting factors to hemophiliacs, the federal Medicare program only makes one payment under Medicare Part B. Under the statutory formula, the actual payment from Medicare equals 76% of the AWP for the clotting factor used. We get 76% of AWP because the law directs Medicare to pay 80% of the allowable cost, which is statutorily set at 95% of AWP. The provider must collect the other 20% of the 95% allowable cost—the co-pay—from either the patient, private insurance, or the state Medicaid program. In the case of Care For Life, roughly 90% of the time we are successful in collecting some portion of that 20% co-payment.

With the reimbursement based on AWP, Care For Life performs all of the services associated with providing the clotting factor. These services include having pharmacists on staff to dispense and track drug interactions, nurses, administrative personnel, shipping, storage, training, supplies, and the cost of advancing the money used to purchase the clotting factor, to name a few.

Care For Life, like many of the providers upon which the Medicare system relies, is a for-profit enterprise. Just like any other business, we must make a reasonable profit margin, or our investors will put their money elsewhere. After taxes, we are making roughly 7%, which I believe is a reasonable return. It is much less than the margins earned by some of the country's telecommunications companies, car companies, and entertainment companies, but enough so that it makes sense to be in this line of business.

If the reimbursement mechanism were changed so that reimbursement was materially decreased, providers like Care For Life would be forced to send patients back to the hospital. That in turn would ultimately lead to increased cost to the Medicare and Medicaid programs, and a decrease in the quality of care received by individuals with hemophilia. That is an outcome that I am confident that this Committee will work to avoid.

Again, I thank you for holding this hearing and for giving me an opportunity to testify. I share your concerns and I applaud your efforts to develop a reasoned approach to Medicare reimbursement. I welcome any questions that you may have.

Mr. GREENWOOD. Thank you, Mr. Martyn. Mr. Connaughton for 5 minutes.

#### TESTIMONY OF THOMAS A. CONNAUGHTON

Mr. CONNAUGHTON. Mr. Chairman, I am President of the American Association for Homecare. Our association includes the full spectrum of the home care industry, including providers of inhalation and infusion therapies in the home setting. Drugs provided in these therapies have been relevant to this hearing.

I am accompanied by Dr. JoAnn Lamphere of the Lewin Group. At our request Lewin conducted a survey of companies offering inhalation and infusion therapies across the country to determine the costs of providing those therapies in the home. Dr. Lamphere will report on Lewin's analysis of this survey and after making a few general statements I will defer to her.

I want to highlight that the pharmaceutical products used in inhalation and infusion therapies are not simply oral medications. In the case of respiratory medications these drugs must be utilized in conjunction with nebulizers. Infusion drug therapy involves primarily the administration of the drug into the body through a needle or catheter. These therapies cannot typically be administered without a complex array of services.

There are some fundamental principles that are important to understand regarding home care and Medicare reimbursement for prescription drugs.

First, our members provide these products in the home, which is significantly more cost effective than providing them in an institution.

Second, the work of the home care provider begins with a prescription. The provider must furnish the drug prescribed by the physician and is not engaged in the selection of a particular product.

Third, administering pharmaceuticals in the home setting involves a number of functions and services performed by the home care provider. These services include the preparation of patient specific sterile drugs, comprehensive training of patients and often their families, and clinical monitoring to prevent infections and other potentially life-threatening complications. Trained professionals are on call on a 24-hour basis. In most cases providing these services is more costly than the drug itself, as the Lewin report will underscore.

Fourth, unlike managed care, which pays for a product plus services, the sole reimbursement under Medicare Part B for these products is for the drug itself. The difference between the reimbursement rate and the cost of the drug must cover all the services. Outside of a small dispensing fee for respiratory drugs, there is no fee schedule for our services, unlike the physicians schedule.

Fifth, Medicare coverage for infusion therapies is very limited, and Medicare is losing the advantage of efficiencies provided in the home setting that the private sector is taking advantage of.

Sixth, we have not been able to make a recommendation for replacement of the AWP system, and I am somewhat comforted that there has been a lot of questions from everyone who has come up here. It is very complex and there are so many variables. That is why we advise you to proceed with care. If, however, Congress revises the reimbursement system for Medicare Part B drugs, it should make certain that it provides for reimbursement of all the services and functions involved in providing these therapies in the home setting based on standards that are widely used in private sector. It should further expand the coverage of infusion therapies for Medicare beneficiaries.

H.R. 2750, introduced by Mr. Engel and others earlier this year, addresses these issues in the context of infusion therapy. We believe this approach is equally appropriate for inhalation therapies.

Dr. Lamphere?

[The prepared statement of Thomas A. Connaughton follows:]

PREPARED STATEMENT OF THOMAS A. CONNAUGHTON ON BEHALF OF THE AMERICAN ASSOCIATION FOR HOMECARE

Mr. Chairman, my name is Tom Connaughton. I am President of the American Association for Homecare ("AAHomecare"). Our Association was formed by the merger of three national associations on February 1, 2000. We are the only national association that represents every line of service within the homecare community. Our members include providers and suppliers of home health services, durable medical equipment (DME) services and supplies, infusion and respiratory care services, and rehabilitative and assistive technologies, as well as manufacturers and state associations.

We thank you for the opportunity to discuss the Medicare reimbursement system for pharmaceuticals administered to beneficiaries by homecare providers and suppliers, in particular, home infusion therapies and inhalation therapies administered to respiratory patients. Homecare providers and suppliers save Medicare money by treating patients in the most cost-effective setting—their homes. The savings gen-

erated by treating patients at home can be dramatically cost-effective when compared to the cost of the same therapy administered in an institutional setting.

Joining me is JoAnn Lamphere (Dr.P.H.) of The Lewin Group. At the request of our association, The Lewin Group conducted a survey of providers and suppliers of inhalation and infusion therapies in order to determine the costs associated with these therapies. The Lewin Group has prepared a report analyzing the results of this survey. To our knowledge, it is the most definitive report on the subject to date. Dr. Lamphere will summarize the findings of that report and, of course, a complete copy is attached for your information.

I want to begin by making an important distinction between infusion and inhalation therapies administered to patients in their homes and conventional outpatient drugs such as pills and "patches." The key difference is that pills and patches do not require professional services to administer. An individual can consume a pill or apply a patch himself after obtaining it from a retail or "traditional" pharmacy. In contrast, infusion and inhalation therapies cannot be administered to patients at home without a complex array of professional services. These medications are provided only on the prescription of a physician and as required by regulatory, accrediting and pharmacy licensing bodies, are prepared in high-tech, sterile settings similar to those found in a hospital. These services ensure the safe and effective administration of infusion and inhalation therapy in the home.

As we begin this discussion, it is also important to note that homecare providers and suppliers are not paid separately for these important services. Medicare does not have a separate benefit for these homecare therapies. Infusion and respiratory medications furnished to homecare patients are covered under the Medicare DME benefit. This means that the only items that are explicitly covered and reimbursed are the drugs, the equipment, and the supplies. Unlike other health care professionals, homecare providers and suppliers do not have a mechanism that reimburses the services necessary to administer the drugs in addition to the reimbursement for the drugs. By comparison, the private managed care sector has recognized the tremendous cost-savings associated with homecare and it continues to provide coverage for a growing list of home infusion and inhalation therapies. Moreover, such organizations contract with providers for extended periods of time, guarantee tremendous volume, and structure their contracts with both a fee for the drug and a per diem to assist in covering the providers' costs of services.

#### INHALATION THERAPY

Inhalation therapy is administered to patients with respiratory disease, including, for example, chronic obstructive pulmonary disease (COPD). COPD is the fourth leading cause of death in the United States, affecting 16 million people.<sup>1</sup> COPD includes a number of chronic respiratory diseases such as emphysema, chronic bronchitis, and asthma. Individuals with COPD have a progressive illness. The disease can be stabilized, but it cannot be cured. Inhalation therapy is used to manage COPD throughout the course of the disease, but in the more advanced stages of COPD, other therapeutic interventions may be required.

Specifically, inhalation therapy is the process through which a drug or a combination of drugs is delivered into the airways and inhaled directly into the lungs via a device called a nebulizer. These drugs may include beta-adrenergic bronchodilators, anticholinergic bronchodilators, mast cell stabilizers, anti-inflammatory steroids, antibiotics, and sputum liquefiers. Patients receiving inhalation therapy at home are monitored by respiratory therapists and highly trained pharmacists. Inhalation therapies reduce acute exacerbations of COPD, saving the Medicare program money in emergency room visits and inpatient stays.

#### INFUSION DRUG THERAPY

Private sector insurance plans and private managed care plans increasingly have embraced home infusion drug therapy since the 1980's. Antibiotic therapy, chemotherapy, and pain management are among the spectrum of infusion therapies that are now commonly provided to patients in their homes. Currently, there are over twenty different drug therapies being offered in the home and other outpatient settings in the private sector. The private sector plans and payers typically recognize expressly and separately the professional services necessary to provide infusion drug therapy in a safe and effective manner in the home setting.

<sup>1</sup> See National Institutes of Health, Global Initiative For Chronic Obstructive Pulmonary Disease, April 2001; Agency for Health Care Quality Research Evidence Based Practice Guidelines, Management of Acute Exacerbations of Chronic Obstructive Pulmonary Disease.

Infusion drug therapy involves primarily the administration of the drug into the body through a needle or a catheter. Typically, infusion drug therapy means that a drug is administered intravenously, but it may also apply to situations where drugs are provided through other parenteral (non-oral) routes. Generally, infusion drug therapies are used only when less invasive means of drug administration are clinically unacceptable or less effective. A team of patient service representatives, clinical pharmacists, high tech infusion nurses, and delivery and reimbursement professionals support patients and their caregivers throughout their treatment. These services are inextricably linked to the therapies and are often mandated by accrediting bodies whose standards ensure quality delivered in an alternate site setting.

Providing infusion therapies at home has several advantages over hospital-based therapy. Most patients prefer to receive such therapies at home rather than in the hospital or in a skilled nursing facility. Homecare therapy allows many patients to lead normal lives throughout the duration of the therapy; it enables terminally ill patients to spend valuable time with their families and loved ones. Also, the ability to administer these therapies in the home reduces the risk of hospital-acquired infections that are sometimes associated with prolonged in-patient stays. In most cases, the cost of infusion drug therapy when properly provided in the home is far less than the cost of such care in the hospital.

#### MEDICARE COVERAGE OF HOME RESPIRATORY AND INFUSION INHALATION THERAPIES

It is important to note that Medicare covers very few of the infusion drug therapies when provided at home. Further, as I stated above, Medicare does not have a separate inhalation therapy benefit or a home infusion therapy benefit. Medicare coverage for these therapies in the home is found only under the DME benefit—but only when equipment such as a nebulizer or an infusion pump is necessary. The fact that coverage for these therapies is limited to the DME benefit is a very important point in understanding the homecare community's issues with drug reimbursement, because the DME benefit explicitly covers only the drugs, supplies, and equipment. There is no recognition of the professional services and other functions that are widely recognized as necessary to providing inhalation and infusion drug therapies in the home in a safe and effective manner.

The Medicare program's lack of recognition of these professional services is illogical, potentially threatening to beneficiaries, and contrary both to how clinicians define and the private sector plans cover these therapies. The clinical value and necessity of the provision of professional services to deliver inhalation and infusion therapies is reflected in various accreditation standards commonly used by private sector payers, such as the standards established by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Indeed, private payers pay for these services as a specific component of the benefit. The Lewin Group's analysis provides a good picture of the costs involved in providing such services.

These therapies require specialized pharmacy services. Such services include the compounding of many of the drugs in a sterile setting, responding to emergencies and questions regarding therapy, and participating in the training and education of the patient (and often the patient's family). These therapies also require the services of a nurse or respiratory therapist to perform a variety of functions, including patient screening and assessment, patient training regarding administration of the pharmaceuticals, and general monitoring of the patient's health status. In the case of infusion therapy, these services also include care for the infusion site, and monitoring of the catheter exit site for signs of infection or other complications. In addition, the drug, supplies, and equipment are delivered to the patient's home often within four hours of the prescription. Patient satisfaction and other outcomes are measured and reported to accrediting organizations as part of quality improvement programs. Finally, staff, including licensed pharmacists, pharmacy technicians, respiratory therapists, and registered nurses, are on call 24 hours a day.

It is important to underscore that none of the specialized pharmacy services is covered under any other Medicare benefit. In a minority of cases, Medicare home infusion patients may meet the "homebound" requirement and qualify for the home health benefit. In such instances, the nursing services described above would be covered under that benefit. For all other Medicare Infusion Patients, the nursing services are not covered by the home health benefit.

#### AVERAGE WHOLESALE PRICE AND DRUG PRICING ISSUES

Much has been said about how Medicare pays for the few outpatient drugs that are covered currently. The use of the average wholesale price (AWP) as the principal basis for determining reimbursement for drugs has received much criticism recently

as being an inaccurate reflector of the physicians' and pharmacists' costs for these drugs. There is little question that these criticisms are correct—if the payment “buys” drugs only. In actual fact, the drug payment calculated on the basis of AWP has been used for far more than that. With regard to inhalation and infusion therapy in the home setting, the drug payment is the only available payment mechanism for needed functions that are essential to providing good quality care. In other words, the spread between the providers and suppliers' acquisition cost and the Medicare reimbursement under Medicare Part B must cover all functions and services. The acquisition cost of the drug is only a fraction of the overall cost of caring for these patients at home.

The conclusions of the Lewin report, which Dr. Lamphere will explain in more detail, reinforce the point that the cost of the drugs represents only one small portion of the overall cost of caring for these patients in need of inhalation or infusion therapy. Indeed, the cost of goods represents 26% of total costs while direct patient care costs average 46% and indirect costs such as accreditation, information systems, and Medicare/Medicaid regulatory compliance amount to another 25%.

In the case of infusion therapies delivered to Medicare beneficiaries, providers, and suppliers, costs exceed the revenues received under Medicare. For respiratory medications, providers and suppliers report an average margin of 9.2% after taxes, which is considerably less than the average after tax margin of 14.4% reported by companies on the S&P index for the same time period in 2000.

It is important to note that homecare providers are not engaged in the selection of a particular drug. Physicians prescribe exactly which drugs should be used. The services furnished by homecare providers and suppliers are triggered by the physician's prescription. Their jobs begin when they receive the physician's order.

Policymakers simply cannot look at drug payment as an isolated issue, separate from the other workings of a particular therapy. Reducing drug payments dramatically, without corresponding changes in other aspects of the payment methodologies, would truly strain the ability of suppliers and providers to continue to provide these drug therapies to Medicare beneficiaries. Indeed, homecare providers and suppliers are in a far more tenuous position regarding drug reimbursement than are other providers because they receive *no payment whatsoever* for the important functions and services. Reimbursement for drug therapies delivered in the home is tied solely to the drug supplies and equipment. There is no fee schedule for services. These necessary professional services must be recognized, and they should be reimbursed.

While we have analyzed the AWP system and possible alternatives, we have not been able to develop a recommendation for the Subcommittees for a system that accurately determines the cost of products to providers and suppliers. These costs vary so widely among providers and suppliers that it is difficult to conceive of a system that accurately accounts for all of these variables. Accordingly, we urge Congress to proceed with caution. However, if Congress contemplates changing the reimbursement system under Part B for drugs administered in the home, it is critical that it recognizes the services involved and provide a framework for reimbursing them. It is not an option, in our opinion, to limit payment and coverage strictly to what is covered under the DME benefit. If Medicare beneficiaries receive only what the DME benefit currently recognizes—the drug, supplies, and equipment (pump or nebulizer)—then the level of care for the Medicare beneficiaries will be far less than that commonly provided in the private sector. Indeed, there are questions whether there will be access for Medicare beneficiaries at all. That result would be neither fair nor clinically appropriate. Medicare beneficiaries often are less able to deal with the complexities of these technical homecare therapies than are people who are decades younger.

#### RECOMMENDATIONS

We believe that it is important to establish accurate definitions of home respiratory and infusion therapy, create quality standards based on those currently and widely used in the private sector, and establish a fee schedule that reflects all the covered components of the therapies. H.R. 2750, introduced earlier this year by Congressman Engel of New York, Congressman Rush of Illinois, Congressman Towns of New York, and Congresswoman Hart of Pennsylvania, would do exactly that for Medicare coverage of home infusion therapy. This bill would remove coverage of home infusion therapy from the DME benefit and establish a new benefit that accurately reflects how these therapies are and should be provided. If enacted, this bill will bring the Medicare program in-line with the private sector as to how these therapies are covered and defined. We believe this approach is equally appropriate for inhalation therapies provided in the home if Congress revises the reimbursement system for Medicare Part B and drugs.

Mr. Chairman, AAHomecare thanks you for the opportunity to present views on behalf of our member companies. Please do not hesitate to call upon us for additional information.

#### TESTIMONY OF JoANN LAMPHERE

Ms. LAMPHERE. Mr. Chairman, my name is JoAnn Lamphere. Thank you for the opportunity to present key findings of the Lewin Group's study. The significance of this study is that it supplies the most current and extensive estimates of the cost of respiratory and infusion therapies and the cost of the services that accompany quality patient care to Medicare beneficiaries in the home.

This past summer the Lewin Group surveyed 19 home pharmacy companies that served Medicare patients in all 50 States. A description of the study's analytic approach is in our report. Key findings of the study include pharmacy, nursing coordination, patient education, and other direct costs account for 46 percent of the total costs incurred by pharmacies providing respiratory and infusion therapies to Medicare patients. Medicare does not currently recognize these costs. The acquisition cost of the drug itself accounts for 26 percent. Indirect costs and bad debt account for another 28 percent. The distribution of direct patient costs varies by type of therapy. For respiratory therapy service costs equal 46 percent. For home infusion service costs range from 40 percent for chemotherapy to 26 percent for antiinfectives. Pretax operating margins are 20.5 percent for respiratory and negative 22.2 percent for home infusion services. The bottom line after-tax Medicare margin is 9.1 percent, which represents the combined margin for respiratory and infusion therapies provided to Medicare patients by home care providers after corporate income tax and interest and depreciation are recognized.

If we are to assure that Medicare beneficiaries across the United States have access to medically prescribed respiratory and infusion therapies in the home, these companies must continue to be financially viable.

Mr. Chairman, thank you.

[The prepared statement of JoAnn Lamphere follows:]

#### PREPARED STATEMENT OF JOANN LAMPHERE, THE LEWIN GROUP

Mr. Chairman. My name is JoAnn Lamphere, Dr.P.H. I am a Senior Manager in the Health Care Finance Practice of The Lewin Group. Thank you for the opportunity to present key findings of a study that The Lewin Group conducted for the American Association for Homecare. The purpose of this study was to determine the costs to providers associated with the clinical and support services offered to Medicare patients receiving respiratory and home infusion therapies in the home.

The significance of this study is that it provides the most current and extensive estimates of the cost of respiratory and infusion medications and the cost of the associated services that accompany quality patient care. This information should be useful to you in the months ahead as you consider the adequacy of Part B payments for drugs and biologicals under the Medicare program.

This past summer, The Lewin Group surveyed 19 home pharmacy providers. The sample was selected with the intent of representing homecare pharmacy companies nationwide. As a group, the sampled providers serve Medicare patients nationwide in all 50 states. The sampled companies range in size from less than \$1 million to greater than \$1 billion in annual net revenue. Sampled companies served 164,782 respiratory and 2,400 home infusion Medicare patients in CY 2000.

A chief financial officer (or designee) or head pharmacist from each participating company completed a mail-in survey; the information they provided was based on company financial records. The Lewin Group validated data submitted through fol-

low-up telephone interviews and available secondary data sources. The information that respondents provided included Medicare revenues, acquisition cost of goods, cost of pharmacy operations and other direct patient care, and other major costs that accompany the provision of respiratory and home infusion therapies to Medicare patients in the home. (Respondents were directed to exclude any costs and revenues associated with skilled nursing services that are reimbursed through home health agency provisions of Medicare.) Respondents were asked to proportionally allocate specified Medicare service expenses based on the volume of Medicare patients they served.

In a study such as this, it is important to assure that findings are not biased by a small sample size. To achieve this objective, a double weighting process was adopted. First the sample of homecare pharmacies was divided into two groups, large companies and small companies, based on volume of their respiratory and home infusion business. Revenues and costs were then pooled at the "large" and "small" company levels and sampled companies' respiratory and home infusion service costs and margins were calculated from these numbers. Next, an additional set of weights was employed in order to ensure that calculations from the sample reflect the industry's distribution of large and small firms with respect to Medicare respiratory and home infusion services. Thus, the Lewin estimates of Medicare product and service costs for respiratory and home infusion therapies and Medicare operating margins were calculated in such a way that they are broadly representative of the homecare pharmacy industry as a whole.

What was learned from this Lewin study? Our key findings include:

- Pharmacy operations, patient care and education, and other direct costs account for 46 percent of the total cost incurred by homecare pharmacies providing respiratory and home infusion therapies to Medicare patients. The acquisition cost of the goods themselves account for about 26 percent of the total cost, on average.
- The distribution of costs for pharmacy operations, direct patient care, and other services varies dramatically by type of therapy. For respiratory therapy, service costs equal 46 percent of the total cost of providing respiratory services in the home. For home infusion therapies, service costs range from a high of 40.2 percent for chemotherapy and 38.7 percent for pain therapy and management to 25.8 percent for anti-infectives and 26.4 for inotropic therapy.
- Indirect costs, such as management systems, regulatory compliance programs, field administration, and bad debt make up the remaining 28 percent of home pharmacy costs.
- We analyzed pre-tax operating margins individually for respiratory and infusion therapies. Pre-tax operating margins are 20.5 percent for respiratory and -22.2 percent for home infusion services. Combined, pre-tax operating margin for both services is 20.4 percent.
- The bottom line after-tax margin for sampled companies is 9.1 percent. This 9.1 percent is the estimated combined margin for respiratory and home infusion services provided to Medicare patients by home pharmacy companies after federal and state corporate income taxes, as well as interest and depreciation, are recognized.

Assuring quality patient care and meeting established patient quality care standards (e.g., accreditation, federal and state licensure and regulatory requirements, etc.) is an essential component of the service homecare pharmacy providers offer to all patients, regardless of whether Medicare reimbursement policies expressly recognize these services.

Currently, Medicare Part B reimbursement for drug products offsets the costs of important patient services for which there is no direct Medicare payment. The financial realities of the health care marketplace that provides respiratory and infusion therapies to Medicare patients at home require a positive after-tax margin in order to attract equity capital for future operations. Thus, if we are to assure that Medicare beneficiaries across the United States have access to medically prescribed respiratory and home infusion therapies in the home, these companies must continue to be financially viable.

Mr. Chairman. Thank you for the opportunity to present these findings from The Lewin Group's study. A copy of the full report, on which this testimony is based, is provided for your consideration.

Mr. GREENWOOD. Thank you very much for your testimony. Dr. Emanuel for 5 minutes.

**TESTIMONY OF EZEKIEL EMANUEL**

Mr. EMANUEL. Thank you, Mr. Chairman and members of the subcommittee, for inviting me to testify. I am Ezekiel Emanuel, an oncologist and bioethicist, and I work at the NIH as the Chair of the Department of Bioethics. I also am Chairman of the American Society of Clinical Oncology's Task Force on Quality of Cancer Care.

Let me start by saying what I am not. All my life I have worked in an academic setting at Dana-Farber Cancer Institute at the NIH, and I have never once billed Medicare for any chemotherapy I administer, so I know very little about AWP.

The primary purpose of my testimony, however, is to talk to you about a study we conducted to look at the use of chemotherapy at the end of life. This is an area I've been interested in for about 15 years. As you know, there's widespread perception among the public that dying cancer patients receive too much chemotherapy. Conversely, my colleagues believe that dying patients and their families often demand chemotherapy and that they use chemotherapy judiciously at the end of life to enhance quality of life and prolong life. Ironically, there is no data on this subject and it's never been looked at before. We looked at nearly 8,000 patients in Massachusetts who died of cancer. Let me just summarize six of our findings.

First, in the last 6 months of life about 33 percent of patients who died of cancer received chemotherapy and almost a quarter of patients received chemotherapy in the last 3 months of their life.

When we compared—second point, when we compared patients who had chemotherapy responsive tumors like breast cancer, colon cancer, ovarian cancer, with patients who had at that time chemotherapy unresponsive tumors, tumors that did not shrink with chemotherapy like pancreatic cancer or liver cancer or gall bladder cancer, we found no difference in the frequency with which the chemotherapy was given. So it was given as frequently to chemotherapy responsive tumors as chemotherapy unresponsive tumors.

Third, dying patients who were younger were much more likely to get chemotherapy than older patients regardless of cancer type.

Fourth, how long dying patients receive chemotherapy, however, differed very much by the type of cancer patients had, so that those patients who had chemotherapy unresponsive tumors like pancreatic cancer or liver cancer got chemotherapy for only one cycle whereas those people who had breast cancer and colon cancer tended to get more chemotherapy.

Fifth, unlike lots of other previous studies we found that patients who received chemotherapy at the end of life had substantially higher Medicare costs than patients who did not receive chemotherapy, up to a third more.

Finally, let me make the point that these data are not unique to Massachusetts. We did a small sample just to verify looking at California patients and found very similar data, although the exact numbers varied.

How might these data affect the hearing here? One of the important questions is why are people getting chemotherapy at the end of life? What motivates people? There are several potential explanations. Let me highlight several.

First, I have to admit I can't tell you from these data exactly why each patient got chemotherapy. We just looked at the Medicare data and it's very hard to draw motivations. But one potential explanation is that many cancer patients, as mentioned by Congressman Ganske, need or want chemotherapy at the end of life, especially when they get diagnosed with a terminal illness, they go to an oncologist, they have no previous relationship and they want to try anything. Oncologists acquiesce, give the chemotherapy, and patients then find out they may not like it and that is why you get a lot of patients getting only one cycle of chemotherapy.

Another potential explanation is that chemotherapy does, we know, improve quality of life of patients. It's very hard for those of us who are healthy, who have never had cancer, who recognize the side effects, the nausea, the vomiting, baldness, that this might improve quality of life, but there are a number of studies showing that with lung cancer, colon cancer, ovarian cancer, chemotherapy improves pain and improves quality of life of dying patients.

A third potential explanation is that we're just uncertain about this, how long in fact are they going to live, and we are always cautious, so we would use chemotherapy.

A fourth potential explanation is that oncologists may give chemotherapy for a financial reimbursement, the spread between AWP and what they get.

I want to emphasize from my data I can't tell you which of these explanations is right, and we need a lot more research to tell how much these factors influence people. But one of the major concerns by our study I think is revealed when you contrast it with other data we have from Medicare, and I want to highlight data from colleagues of mine at Memorial Sloan-Kettering. They recently looked at chemotherapy administered to patients with colon cancer where we know the chemotherapy prolongs life and can cure patients, and they revealed that only 55 percent of Medicare patients with colon cancer actually got chemotherapy. This is chemotherapy for which doctors would be reimbursed the same amount as in other cases, and so we know there are cases where there is overuse and cases where there is under use.

And this leads me to this issue: While we are focusing on costs here, let me suggest that there is a bigger issue, and that is that we as oncologists cannot guarantee Americans who are diagnosed with cancer get optimal cancer care. Sometimes they may get too much chemotherapy, sometimes too little, even when oncologists are being reimbursed to give them chemotherapy. And I think that what we really need to figure out is how we're paying for quality cancer care and that people who need the drugs get the drugs, and that's actually why I have been working with ASCO on a \$5 million project to try to figure out how we can get quality cancer care and what are the barriers to getting people the right drugs at the right time that prolongs their life and improves their quality of life.

Thank you very much for inviting me, and I will be happy to answer any of your questions.

[The prepared statement of Ezekiel Emanuel follows:]

PREPARED STATEMENT OF EZEKIEL EMANUEL, CHIEF, CLINICAL BIOETHICS DEPARTMENT, WARREN G. MAGNUSON CLINICAL CENTER, NATIONAL INSTITUTES OF HEALTH

There is substantial concern about end-of-life care provided to Americans. In particular, a number of commentators are concerned that dying cancer patients are frequently overtreated with chemotherapy. Critics contend that many oncologists overtreat dying patients with chemotherapy because they are reluctant to accept death and apprehensive about discussing end-of-life care.<sup>1,2,3</sup> Indeed, some critics contend that oncologists prey on their patients' vulnerability, implying that chemotherapy is the vehicle of hope, and pressing them to try it before reconciling themselves to death.<sup>4</sup> Oncologists respond that it is terminally ill patients who demand treatment. More importantly, oncologists contend that they use chemotherapy prudently in patients at the end of life, when it is likely to provide symptom relief and enhance dying patients' quality-of-life.

How can we determine if chemotherapy is used too frequently for terminally ill cancer patients? There are no standards for the appropriate use of chemotherapy at the end of life based upon either randomized controlled trials or expert, consensus guidelines. While there are some data on treatment of patients with metastatic cancers,<sup>5</sup> even basic data on how frequently cancer patients are given chemotherapy in the months before death are lacking. To explore whether chemotherapy is used prudently and rationally at the end of life, we separately examined its use among Massachusetts and California Medicare beneficiaries who died of cancer in 1996. Dividing patients into two groups according to whether they died of cancers responsive or unresponsive to chemotherapy, we evaluated the use of chemotherapy, and the expenditures in the last year of life.

#### METHODS

**Identifying Cancer Decedents:** To focus only on persons who died from cancer—not merely with cancer—based on the primary cause of death listed in the death certificate, we followed a 3-step process. First, in both Massachusetts and California we studied fully entitled Medicare beneficiaries who died in 1996, were at least 66 years old at death and were not enrolled in Medicare's End Stage Renal Disease program. Decedents 66 years of age were selected to ensure we obtained a full year of Medicare expenditure data prior to death. We studied all such decedents in Massachusetts and 5% in California. Second, we merged HCFA's denominator files with each state's 1996 death certificate files. In Massachusetts, 42,452 Medicare decedents met the criteria. In merging the files we used social security number (SSN), date of birth (DOB), date of death (DOD) and sex. A match was accepted if either of the following conditions was met: 1) there was a perfect match on SSN and either sex or both DOB and DOD or 2) a match on at least 7 of SSN digits and a perfect match on sex, DOB, and DOD. Of the 42,452 decedents, there was a match between the HCFA files and death certificates for 39,447 (92.9%). Only beneficiaries continuously enrolled in both Parts A and B Medicare insurance and who were not enrolled in an managed care organization over the entire last 12 months of life were retained, yielding 34,131 Massachusetts decedents. Third, we selected the 7,919 decedents whose primary cause of death listed on the death certificate was cancer.

In California, the same general protocol was applied to a random 5% of Medicare enrollees yielding 4,715 total decedents overall, of which 956 died of cancer.

**Classifying Cancer Types:** We classified breast, colon, and ovarian cancers as chemotherapy responsive solid cancers. Multiple chemotherapeutic agents shrink these cancers, and randomized trials have shown chemotherapy to be effective in prolonging lives of patients at least as adjuvant therapy. We classified pancreatic, renal cell, hepatocellular, gallbladder, cancers, and melanoma as chemotherapy unresponsive solid cancers. In 1996, these cancers were known to be "refractory to virtually all chemotherapeutic agents" such that the general consensus in standard textbooks is that "there are no particularly compelling cytotoxic chemotherapeutic agents [with which] to treat" them.<sup>6</sup>

We examined data for other cancers that we did not categorize as responsive or unresponsive. For example, while prostate cancer is generally considered a chemotherapy unresponsive solid cancer, hormonal injections may appear in claims data as chemotherapy. To avoid uncertainty, prostate cancer is reported separately. Lung cancer also examined separately because using claims data, it is impossible to differentiate lung cancers into small cell and non-small cell (NSCLC) tumors. Furthermore, while small cell cancers are chemotherapy responsive, using chemotherapy for metastatic non-small cell lung cancers is highly controversial.<sup>7</sup> Data suggest that chemotherapy for NSCLC extends life by 6 weeks and may improve quality-of-life despite toxicities.<sup>8,9,10</sup> Finally, hematological malignancies, encompassing both acute

and chronic leukemias, Hodgkin's disease, and all non-Hodgkin's lymphomas, were analyzed separately. Although they are chemotherapy responsive, patients may die acutely from treatment related toxicities.

**Identifying the Use of Chemotherapy:** Patients who had claims in the inpatient, outpatient or physician/supplier Medicare files for chemotherapy agents, chemotherapy administration, or the medical supervision of chemotherapy were considered to as having received chemotherapy. The codes used were: intravenous chemotherapy agents—HCPCS codes 964XX, 965XX, J9000-9999; chemotherapy administration—IC Procedure 99.25, HCPCS codes Q0083-Q0085; medical evaluation for chemotherapy—ICD Diagnosis V58.1, V66.2, and V67.2. It is possible that our method of identifying chemotherapy missed patients who received oral chemotherapeutic agents. Patients without claims using these codes were classified as not having chemotherapy.

We examined chemotherapy use for decedents for 30-day periods from the date of death back for 12 months.

**Expenditure Data:** Total expenditure is calculated as the sum of HCFA payments and payments from other sources of insurance for Medicare covered services. The average payment per person from other insurance accounts for only 0.15% of costs. Expenditures for each decedent are calculated from 5 HCFA files: 1) Medicare Provider Analysis and Review (MedPAR), including acute hospitalizations, long term hospitalizations, and skilled nursing home care; 2) Hospital outpatient; 3) Part B physician-supplier; 4) Home health care; and 5) Hospice. Durable medical equipment (DME) expenses were excluded, but in Massachusetts, they contributed just \$400 per person over the last year of life.

## RESULTS

**Frequency of Chemotherapy in the Last Months of Life:** Figure 1 shows that 41% of our study population in Massachusetts received chemotherapy in the last year of life. Fully 33% of Massachusetts cancer decedents received chemotherapy in the last 6 months of life, 23% in the last 3 months of life, and 9% of cancer decedents received chemotherapy in the very last month of life.

Table 1 provides data on the proportion of terminally ill cancer patients treated in Massachusetts with chemotherapy in the last 6, 3 and 1 months of life. Patients who died of hematological malignancies received chemotherapy most frequently, with more than half getting chemotherapy in the last 6 months of life and 19% in the last month of life. Massachusetts patients with chemotherapy unresponsive solid cancers received chemotherapy at about the same frequency as patients with chemotherapy responsive solid cancers (Table 1). Among patients with chemotherapy unresponsive solid cancers taken together (pancreatic, hepatocellular, gallbladder, and renal cell cancers and melanoma) 23% received chemotherapy in the last 3 months of life, which was the same as the percentage of patients with chemotherapy responsive cancers (breast, colon, ovarian) that received chemotherapy.

An interesting example of the use of chemotherapy at the end of life is pancreatic cancer. In the last 6 months of life, 33% of Massachusetts patients dying of pancreatic cancer received chemotherapy, 25% in the last 3 months, and 8% in the last month of life. On May 15, 1996, the FDA approved gemcitabine as the first agent shown to be effective in pancreatic cancer. Prior to this date, when there were no effective agents, 28% of patients dying of pancreatic cancer received chemotherapy in the last 6 months of life. After May 15th, 37% received chemotherapy (one-sided  $p=0.04$ ).

A comparison of the chemotherapy unresponsive melanoma and renal cell cancer with chemotherapy responsive breast and colon cancers is also instructive. Of patients dying of melanoma, 21% received chemotherapy in the last 3 months of life and 10% in the last month of life. Similarly, among patients dying of renal cell cancer, 22% received chemotherapy in the last 3 months of life and 7% in the last month of life. Surprisingly the frequency of chemotherapy for dying breast and colon cancer patients was almost identical. 22% of patients dying of breast cancer received chemotherapy in the last 3 months and 8% in the last month of life. Similarly, 23% of patients dying of colon cancer received chemotherapy in the last 3 months and 7% in the last month of life.

There are no substantial differences in the use of chemotherapy by sex (Table 1). However, the use of chemotherapy at the end of life is age related. Among Massachusetts patients 65-74 32% received chemotherapy in the last 3 months of life, compared to 22% for patients 75 to 84 year old, and 11% for patients over 85 years of age (Table 1). These variations by age were similar in chemotherapy unresponsive and responsive solid cancers (Table 2). Overall, 13% of 85 year olds with chemotherapy unresponsive solid cancers received chemotherapy in the last 3 months of

life compared to 10% of 85 year olds with chemotherapy responsive solid cancers (Table 2).

**Number of Months of Chemotherapy in the Last Months of Life:** Among Massachusetts patients who received chemotherapy in the last 6 months of life, 41% had a short "trial," just one month or less of chemotherapy, with 36% receiving chemotherapy for 1 to 3 months, 23% 4 or more months of chemotherapy (Table 3). The number of months of chemotherapy did not depend on sex, but did depend upon age (Table 3).

Importantly, the chemotherapy responsiveness of the solid cancers was associated with a difference in the number of months of chemotherapy provided to decedents (Table 3). Among Massachusetts patients dying of chemotherapy unresponsive tumors who received chemotherapy, over half received 1 month or less of chemotherapy and 31% received chemotherapy for 1 to 3 months. Conversely, among patients dying of chemotherapy responsive cancers who received chemotherapy a third received 1 month or less of chemotherapy and 40% received chemotherapy for 1 to 3 months of the last 6 months of life. Notably, 17% of patients dying from chemotherapy unresponsive cancers had 4 or more months of chemotherapy (Table 3).

Returning to patients with pancreatic cancer, 49% received chemotherapy for 1 month or less, 34% for 1 to 3 months and 3% during each of the last 6 months. For patients dying of breast cancer, 32% received chemotherapy for 1 month or less, 39% for 1 to 3 months and 5% across all 6 final months.

**The Use of Chemotherapy and Expenditures:** Annual expenditures for dying Massachusetts cancer patients who received chemotherapy in the last 6 months of life were 32.5% higher than patients who did not receive chemotherapy (\$39,707 v. \$29,974) (Table 4). Annual expenditure for patients with chemotherapy unresponsive cancers who received chemotherapy was \$33,365 about 10% less than the expenditure for patients with chemotherapy responsive cancers who received chemotherapy (\$36,684). Expenditures for patients with chemotherapy unresponsive cancers who received chemotherapy were 20% more than for patients with the same cancers who did not receive chemotherapy (\$33,365 v. \$27,737), while expenditures for patients with chemotherapy responsive cancers who received chemotherapy were 23.9% more than for patients with the same cancers who did not receive chemotherapy (\$36,684 v. \$29,610).

**Comparison with Cancer Decedents from California:** We used decedents our sample of 956 cancer decedents from California to test whether our findings in Massachusetts might apply more generally (Table 5). Among California cancer decedents, 26% received chemotherapy in the last 6 months of life, 20% in the last 3 months and 9% in the last month of life. Among decedents with chemotherapy responsive tumors, 17% received chemotherapy in the last 3 months of life compared to 20% for the chemotherapy unresponsive tumors.

Similarly, use of chemotherapy at the end of life was age related in California for both chemotherapy responsive and unresponsive cancers. Among decedents aged 65-74, 26% of those with chemotherapy responsive tumors compared to 32% of those with chemotherapy unresponsive tumors received chemotherapy in the last 3 months of life. Similarly, among decedents aged 75-84 19% of those with responsive tumors compared to 18% of decedents with unresponsive tumors received chemotherapy in the last 3 months of life. Overall, 25% of patients with chemotherapy responsive tumors receiving chemotherapy received less than 1 month of chemotherapy while 35% of those with chemotherapy unresponsive tumors did so.

#### DISCUSSION

This study provides insight into the frequency of use of chemotherapy at the end of life. Overall 33% of Medicare patients dying of cancer in Massachusetts in 1996 received chemotherapy in the last 6 months of life and nearly a quarter in the last 3 months. Most surprisingly, patients dying of chemotherapy unresponsive cancers, such as pancreatic, gallbladder, renal cell, and hepatocellular cancers, were just as likely to receive chemotherapy at the end of life as patients dying of chemotherapy responsive cancers, such as breast, colon, and ovarian cancers. This suggests overuse of chemotherapy at the end of life, at least among patients with chemotherapy unresponsive cancers.

Traditionally, to document over- and underuse of health care services, studies compare claims data with optimal practices established by randomized controlled trials or by expert, consensus panels. Lacking randomized trials or consensus panels to establish standards for the appropriate use of chemotherapy at the end of life, we examined tumor responsiveness to chemotherapy. Cancers are traditionally divided in those that are chemotherapy responsive, in which chemotherapy can commonly induce complete and partial responses, compared to those in which chemo-

therapy rarely leads to tumor shrinkage. In our data, lack of responsiveness of the cancer to chemotherapy did not reduce the prevalence of chemotherapy use. Patients with unresponsive cancers were just as likely to receive chemotherapy in the last few months of life as patients with chemotherapy responsive cancers. Indeed, patients with unresponsive cancers were slightly more likely to receive chemotherapy than patients with lung cancer in which data suggests chemotherapy in the last 6 months of life, may extend life by a few weeks and even palliate symptoms.

Although patients dying of chemotherapy unresponsive solid cancers received chemotherapy as frequently as those with responsive cancers, they received fewer months of chemotherapy. This suggests some selectivity in the use of chemotherapy at the end of life. It is possible that after one cycle of therapy many patients and oncologists are convinced by ineffectiveness and/or the side effects to stop treatment for chemotherapy unresponsive cancers. Nevertheless, 17% of patients receiving chemotherapy for chemotherapy unresponsive cancers received chemotherapy during four or more of the final 6 months of life.

Many reasons may explain the use of chemotherapy at the end of life for patients with unresponsive cancers. The most reasonable explanation may be that patients and families demand to at least “try” to see if chemotherapy might shrink the cancer. Oncologists frequently meet patients for the first time right after they have been newly diagnosed with chemotherapy unresponsive tumors that present a bleak prognosis. These patients and their families often want to try anything that might shrink their cancers. Indeed, data suggest that cancer patients are willing to endure significant side effects for very small prolongations in life.<sup>11,12</sup> Lacking an established relationship with the patient or family and confronting an emotional demand to try anything, oncologists may acquiesce. One cycle of chemotherapy is often sufficient for patients and families to adjust and absorb the realities of the diagnosis, prognosis, and to realize the ineffectiveness of the chemotherapy and the undesirable side effects. That over half of the patients receiving chemotherapy for unresponsive cancers received 1 month or less of chemotherapy strongly supports this explanation. Obviously, additional research is necessary to provide insights into how much of a role patient and family demand plays in the use of chemotherapy at the end of life.

Other potential reasons for the use of chemotherapy at the end of life include uncertain prognosis and time of death, uncertain responsiveness of the cancer to chemotherapy, and use of experimental chemotherapies. These reasons are unlikely to account for our data on chemotherapy unresponsive solid cancers. While the exact date of death cannot be known in advance, cancers, especially chemotherapy unresponsive solid cancers, are unlike the terminal phases of COPD or heart failure; they tend to have a monotonic, unremitting decline to death despite all interventions.<sup>13</sup> Typically within the last three months of life, oncologists can predict, with reasonable certainty that the patient will die in a few months regardless of treatment. Furthermore, there is no real uncertainty about the chemotherapy unresponsiveness of the solid tumors we classified as “unresponsive.” Finally, although some patients may be receiving experimental chemotherapy, this is likely to be rare among Medicare beneficiaries who are often ineligible due to age and comorbidities.

Yet another potential explanation for the use of chemotherapy for patients with unresponsive cancers is that chemotherapy may improve quality of life and palliate symptoms for dying patients even if it fails to prolong life or shrink tumors.<sup>14,15</sup> There are some data supporting the palliative effect of chemotherapy for lung and colon cancer and some suggestions that this might also operate in ovarian cancer.<sup>16,17,18,19</sup> Frequently, emotional functioning and fatigue are the quality-of-life subscales with the most improvement. That these improvements occur without objective tumor responses suggests that they may be related to patient expectations or possibly the placebo effect of chemotherapy, rather than any biological impact.<sup>20</sup> The mechanism by which chemotherapy in terminal phases may palliate without objectively shrinking cancers requires further research.

The similar frequency of chemotherapy use regardless of the responsiveness of the cancer may be because near terminal patients with breast, colon, and ovarian cancers may have been treated with many different chemotherapy regimens and their cancers may have become chemotherapy resistant. In this way, patients dying of chemotherapy responsive tumors may be more like decedents with chemotherapy unresponsive cancers. This does not justify using chemotherapy for unresponsive tumors. It also raises the question of whether providing chemotherapy in the last 3 months of life to nearly a quarter of cancer patients whose tumors have become resistant to chemotherapy is itself an indication of overuse.

This study suggests that use of ineffective chemotherapy consumes substantial medical resources. Annual expenditures for patients who received chemotherapy, regardless of the responsiveness of the cancer, were 32.5% higher than for patients

who did not receive chemotherapy in the last 6 months of life. Among patients who died of chemotherapy unresponsive cancers, the use of chemotherapy in the last 6 months of life was associated with 20% higher annual expenditures, or more than \$5,500 per decedent. The extra amount spent on providing chemotherapy to patients dying of unresponsive cancers is comparable to the average annual expenditure for all Medicare beneficiaries and nearly one third higher than annual per capita health expenditures in the U.S. These data contrast with studies suggesting that compared to “best supportive care” chemotherapy for non-small cell lung cancer does not increase, and may even decrease medical costs.<sup>21,22,23</sup> The disjunction between our results and these studies may arise because of the difficulty in translating results of randomized trials into actual clinical practice. Care protocols in research may limit use of unnecessary interventions, whereas in actual clinical practice use of treatments, hospitalizations, and other interventions vary more. Furthermore, the cost data on best supportive care come only from Canada and are more than a decade old<sup>21-23</sup>, and patients receiving best supportive care were frequently hospitalized, using more hospital days than patients receiving chemotherapy. These old data, especially of hospitalizing patients receiving “best supportive care” reflect practices not found in these data and unlikely to still be common. It may also be that in actual clinical practice patients not receiving chemotherapy may not be receiving “best supportive care” reducing expenditures.

Finally, this overuse of treatment at the end of life is particularly wasteful when placed in the context of the documented underuse of treatments proven by randomized controlled trials to be effective in prolonging life. Studies have shown that only 55% of Medicare beneficiaries receive adjuvant chemotherapy for Stage III colon cancer.<sup>24</sup> Indeed, among 85 year old patients the use of chemotherapy for Stage III colon cancer is 11% less than the frequency of the use of chemotherapy in the last 3 months for 85 year olds with chemotherapy unresponsive cancers. Unfortunately, it appears that there may be overuse of chemotherapies in the last few months of life coincident with underuse of therapies known to be effective in prolonging life.

In health care, Massachusetts is known as a high use and high cost state.<sup>25</sup> A major issue is whether these data on chemotherapy use at the end-of-life are unique to Massachusetts or are generalizable. While there are some differences in the absolute use of chemotherapy for some cancers, our data from California, although limited, suggest a similar pattern of use of chemotherapy at the end of life. In California one in five cancer decedents receive chemotherapy in the last 3 months of life, and this does not differ between chemotherapy responsive and unresponsive cancers. Clearly, these results need to be confirmed in other, larger populations. However, these data show that the situation in Massachusetts is not unique.

This study has some significant limitations. First, the data may not generalize in other ways. Chemotherapy use among decedents under 65 years of age might be different. The strong trends toward greater use of chemotherapy among younger decedents suggests these data might actually underestimate chemotherapy use in the last 6 months of life among cancer decedents of all ages. Chemotherapy use in managed care settings also might differ. Second, we have no data on stage of cancer; some patients may have died from acute toxicities of chemotherapy without being terminally ill. However, data from trials suggest that acute toxic deaths among patients receiving adjuvant therapy are rare, and thus unlikely to account for a substantial proportion of cancer mortality.<sup>26</sup> Indeed, adjuvant chemotherapies associated with high toxic mortality would be used infrequently. Third, the cause of death listed on death certificates is not always accurate. However, listing cancer as the cause of death may be insensitive, but it is specific, and Massachusetts and California are among the states with the most accurate death certificates. Fourth, annual expenditures were calculated but we tracked chemotherapy use only in the last 6 months of life. Decedents who received chemotherapy in the 7 to 12 months before death only are classified in the “no chemotherapy” group, increasing the costs of this group. This makes the difference in expenditures appear smaller than if the comparison had been with decedents who had received no chemotherapy in the entire last year of life. Most importantly, these data provide no explanation for why chemotherapy is provided in any particular case. Additional study is needed to determine the reasons why chemotherapy is used in the last 6 months of life, especially for chemotherapy unresponsive cancers.

#### CONCLUSION

There is substantial disagreement about whether chemotherapy is used appropriately in patients near the end of life. This study demonstrates that one third of patients in Massachusetts receive chemotherapy in the last 6 months of life, even

among those persons dying from chemotherapy unresponsive cancers. Oncologists should reconsider the use of chemotherapy at the end of life.

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#### Frequency of Patients Receiving Chemotherapy in the Last Months of Life

(This will be a figure)

	Massachusetts (N=7,919)
Last 1 month of life .....	9%
Last 2 months .....	17%
Last 3 months .....	23%
Last 4 months .....	28%
Last 5 months .....	31%
Last 6 months .....	33%
Last year of life .....	41%

TABLE 1: Characteristics of Massachusetts Cancer Decedents by Receipt of Chemotherapy in the Last 6 Months of Life

		All Cancer Decedents	Cancer Decedents Receiving Chemo- therapy in Last:		
			6 months of life (N=2,625)	3 months of life (N=1,854)	1 month of life (N=715)
All Cancers .....		7,919	33%	23%	9%
Sex .....	Male .....	3,863	35%	22%	10%
	Female .....	4,056	31%	26%	8%
Age .....	65-74 .....	2,926	44%	32%	12%
	75-84 .....	3,392	31%	22%	8%
	85+ .....	1,601	16%	11%	5%
Chemotherapy Responsive Solid Cancers ..	Total .....	1,627	34%	23%	%
	Breast .....	612	30%	22%	8%
	Colon .....	846	32%	23%	7%
	Ovarian .....	269	47%	30%	7%
Chemotherapy Unresponsive Solid Cancers	Total .....	870	31%	23%	9%
	Pancreas .....	408	33%	25%	8%
	Melanoma .....	84	30%	21%	10%
	Renal Cell .....	147	29%	22%	7%
Other Types of Cancer .....	Hepatic and Gallbladder .....	231	29%	20%	8%
	Lung .....	2,003	28%	19%	7%
	Prostate .....	602	39%	28%	10%
	Hematological* .....	760	51%	42%	19%
	All Other .....	2,057	30%	20%	9%

\* Includes all acute and chronic leukemias, non-Hodgkin lymphomas, Hodgkin's disease, but excludes multiple myeloma.

TABLE 2: Massachusetts Cancer Decedents Receiving Chemotherapy in the Last 3 Months of Life by Cancer Type and Age

		Number of Patients Getting Chemo- therapy in last 3 Months of Life	65-74 (N=2,926)	75-84 (N=3,392)	85+ (N=1,601)
All Cancers .....		1,854	32%	22%	11%
Chemotherapy Responsive Solid Cancers ..	Total .....	377	36%	21%	10%
	Breast .....	135	38%	19%	7%

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TABLE 2: Massachusetts Cancer Decedents Receiving Chemotherapy in the Last 3 Months of Life by Cancer Type and Age—Continued

		Number of Patients Getting Chemo-therapy in last 3 Months of Life	65-74 (N=2,926)	75-84 (N=3,392)	85+ (N=1,601)
Chemotherapy Unresponsive Solid Cancers	Colon .....	191	33%	23%	11%
	Ovarian .....	51	43%	22%	17%
	Total .....	199	30%	22%	13%
	Pancreas .....	101	33%	24%	12%
	Melanoma .....	18	27%	19%	13%
	Renal Cell .....	33	36%	15%	10%
Other Types of Cancer .....	Hepatic and Gallbladder .....	47	23%	21%	15%
	Lung .....	371	28%	12%	6%
	Prostate .....	170	32%	34%	11%
	Hematological* .....	321	54%	44%	17%
	All Other .....	416	26%	20%	11%

\* Includes all acute and chronic leukemias, non-Hodgkin lymphomas, Hodgkin's disease, but excludes multiple myeloma.

TABLE 3: The Number of Months of Chemotherapy Provided to Massachusetts Cancer Decedents Receiving Any Chemotherapy in the Last 6 Months of Life

		1 Month or Less>	1 to 3 Months>	3 Months	Mean Number of Months
All Cancers .....		41%	36%	19%	2.4
Sex .....	Male .....	38%	36%	20%	2.2
	Female .....	45%	36%	16%	2.5
Age .....	65-74 .....	35%	39%	21%	2.5
	75-84 .....	44%	35%	17%	2.3
	85+ .....	59%	28%	11%	1.9
Chemotherapy Responsive Solid Cancers ..	Total .....	33%	40%	22%	2.6
	Breast .....	32%	39%	24%	2.6
	Colon .....	35%	41%	19%	2.5
Chemotherapy Unresponsive Solid Cancers	Ovarian .....	29%	39%	24%	2.8
	Total .....	52%	31%	14%	2.0
	Pancreas .....	49%	34%	14%	2.1
	Melanoma .....	56%	36%	0%	1.8
	Renal Cell .....	51%	37%	10%	2.0
Other Types of Cancer .....	Hepatic and Gallbladder .....	59%	21%	17%	2.1
	Lung .....	45%	39%	13%	2.2
	Prostate .....	30%	31%	31%	3.0
	Hematological* .....	32%	39%	22%	2.7
	All Other .....	50%	33%	14%	2.1

\* Includes all acute and chronic leukemias, non-Hodgkin lymphomas, Hodgkin's disease, but excludes multiple myeloma.

TABLE 4: Expenditures in the Last Year of Life for Massachusetts Cancer Decedents by Receipt of Chemotherapy in the Last 6 Months of Life

		Decedents who Received No Chemo-therapy (N=)	Decedents who Received Chemotherapy (N=)	% Increase for Decedents Receiving Chemotherapy
All Cancers .....		\$29,974	\$39,707	32.5%
Sex .....	Male .....	\$29,729	\$39,539	33.0%
	Female .....	\$30,193	\$39,890	32.1%
Age .....	65-74 .....	\$32,551	\$43,042	32.2%
	75-84 .....	\$31,155	\$36,989	18.7%
	85+ .....	\$24,803	\$34,055	37.2%
	Total .....	\$29,610	\$36,684	23.9%
Chemotherapy Responsive Solid Cancers .....	Breast .....	\$26,817	\$36,277	35.3%

TABLE 4: Expenditures in the Last Year of Life for Massachusetts Cancer Decedents by Receipt of Chemotherapy in the Last 6 Months of Life—Continued

		Decedents who Received No Chemo- therapy (N=)	Decedents who Received Chemotherapy (N=)	% Increase for Decedents Receiving Chemotherapy
Chemotherapy Unresponsive Solid Cancers	Colon .....	\$31,435	\$32,972	4.9%
	Ovarian .....	\$30,870	\$50,400	63.5%
	Total .....	\$27,737	\$33,365	20.3%
	Pancreas .....	\$26,356	\$35,371	34.2%
	Melanoma .....	\$19,982	\$32,717	63.7%
Other Types of Cancer	Renal Cell .....	\$32,923	\$35,735	8.5%
	Hepatic and Gallbladder ..	\$27,911	\$29,275	4.9%
	Lung .....	\$29,750	\$38,967	31.0%
	Prostate .....	\$27,685	\$34,167	23.4%
	Hematological* .....	\$34,430	\$52,619	52.8%
	All Other .....	\$30,861	\$39,830	29.1%

\* Includes all acute and chronic leukemias, non-Hodgkin lymphomas, Hodgkin's disease, but excludes multiple myeloma.

TABLE 5: The Characteristics of California Cancer Decedents by Receipt of Chemotherapy in the Last 6 Months of Life

		All Cancer Decedents	Cancer Decedents Receiving Chemotherapy in Last:		
			6 months of life (N=253)	3 months of life (N=191)	1 month of life (N=85)
All Cancers		956	26%	20%	9%
Sex	Male	437	30%	24%	11%
	Female	519	23%	17%	7%
Age	65-74	323	39%	31%	12%
	75-84	444	25%	18%	9%
	85+	189	8%	6%	3%
Chemotherapy Responsive Solid Cancers		175	25%	17%	6%
Chemotherapy Unresponsive Solid Cancers		108	24%	20%	8%
Other Types of Cancer	Lung	280	23%	17%	8%
	Prostate	83	37%	27%	13%
	Hematological*	112	36%	29%	14%
	All Other	198	25%	19%	9%

\* Includes all acute and chronic leukemias, non-Hodgkin lymphomas, Hodgkin's disease, but excludes multiple myeloma.

## REFERENCES

- <sup>1</sup> Annas GJ. The changing landscape of human experimentation: Nuremberg, Helsinki, and beyond. *Health Matrix* 1992;2:119-140.
- <sup>2</sup> Sontag S. *Illness as metaphor* (New York: Farrar, Strauss, and Giroux 1978).
- <sup>3</sup> McKhann CF. *A time to die* (New Haven, Conn.: Yale University Press 1999) introduction and chapter 1.
- <sup>4</sup> Miller M. Phase I cancer trials: a collusion of misunderstanding *Hastings Center Report* 2000;30(4):34-43.
- <sup>5</sup> Earle CC, Venditti LN, Neumann PJ, et al. Who gets chemotherapy for metastatic lung cancer? *Chest* 2000;117:1239-46.
- <sup>6</sup> Holland JF, Frei E, Bast RC, et al. (eds.) *Cancer Medicine* 5th edition (Hamilton, Ont. Canada: B.C. Decker 2000) chapters 88, 96, 98, 101, 105, 109.
- <sup>7</sup> Tannock IF, Boyer M. When is cancer treatment worthwhile? *N Engl J Med* 1990;323:989-990.
- <sup>8</sup> Cullen MH, Billingham LJ, Woodroffe CM, et al. Mitomycin, ifosfamide, and cisplatin in unresectable non-small cell lung cancer: effects on survival and quality of life. *J Clin Oncol* 1999;17:3188-94.
- <sup>9</sup> Cullen M. "Best supportive care" has had its day. *Lancet Oncology* 2001;2:173-5.
- <sup>10</sup> Ruckdeschel JC. Is chemotherapy for metastatic nonsmall cell lung cancer "worth it"? *J Clin Oncol* 1990;8:1293-1296.
- <sup>11</sup> Slevin ML, Stubbe L, Plant HJ, et al. Attitudes to chemotherapy: comparing views of patients with cancer with those of doctors, nurses, and general public. *BMJ* 1990;300:1458-60.
- <sup>12</sup> Yellen SB, Cella DF. Someone to live for: social well-being, parenthood status, and decision-making in oncology. *JCO* 1995;13:1255-1264.
- <sup>13</sup> Field MJ, Cassel CK. *Approaching death: improving care at the end of life* (Washington, D.C.: National Academy Press 1997) introduction.
- <sup>14</sup> Gough IR, Furnival CM, Burnett W. Patients attitudes to chemotherapy for advanced gastrointestinal cancer. *Clin Oncol* 1981;7:5-11.

<sup>15</sup>Ellis PA, Smith IE, Hardy JR, *et al.* Symptom relief with MVP (mitomycin C, vinblastine and cisplatin) chemotherapy in advanced non-small cell lung cancer. *British J Cancer* 1995;71:366-70.

<sup>16</sup>Anderson H, Hopwood P, Stephens RJ, *et al.* Gemcitabine plus support care (BSC) v. BSC in inoperable non-small cell lung cancer—a randomized trial with quality of life as the primary outcome *British J Cancer* 2000;83:447-453.

<sup>17</sup>Cunningham D, Pyrhonen S, James RD, *et al.* Randomised trial of irinotecan plus supportive care versus supportive care alone after fluorouracil failure for patients with metastatic colorectal cancer. *Lancet* 1998;352:1413-18.

<sup>18</sup>Coyle C, Crump M, Pintilie M, Oza AM. Does palliative chemotherapy palliate? Evaluation of expectations, outcomes, and costs in women receiving chemotherapy for advanced ovarian cancer. *JCO* 2001;19:1266-74.

<sup>19</sup>Burris HA, Moore MJ, Andersen J *et al.* Improvements in survival and clinical benefit with gemcitabine as first-line therapy for patients with advanced pancreatic cancer: a randomized trial. *JCO* 1997;15:2403-13.

<sup>20</sup>Wan GJ, Coune MA, Cella DF. The influence of personal expectations on cancer patients' reports of health related quality of life. *Psycho-oncology* 1997;6:1-11.

<sup>21</sup>Jaakkimainen L, Goodwin PJ, Pater J, Warde P, Murray N, Rapp E. Counting the costs of chemotherapy in a National Cancer Institute of Canada randomized trial in nonsmall cell lung cancer. *JCO* 1990;8:1301-09.

<sup>22</sup>Evans WK, LeChevalier T. The cost-effectiveness of navelbine alone or in combination with cisplatin in comparison to other chemotherapy regimens and best supportive care in stage IV non-small cell lung cancer. *Eur J Cancer* 1996;32A:2249-55.

<sup>23</sup>Berthelot JM, Will BP, Evans WK, Coyle D, Earle CC, Bordeleau. Decision framework for chemotherapeutic interventions for metastatic non-small cell lung cancer. *JNCI* 2000;92:1321-9.

<sup>24</sup>Schrag D, Cramer LD, Bach PB, Begg CB. Age and adjuvant chemotherapy use following surgery for state III colon cancer. *JNCI* 2001; (in press).

<sup>25</sup>Center for the Evaluative Sciences *The Dartmouth Atlas of Health Care* (Chicago: American Hospital Publishing 1996).

<sup>26</sup>Fisher B, Brown AM, Dimitrov NV, *et al.* Two months of doxorubicin-cyclophosphamide with and without interval reinduction therapy compared with 6 months of cyclophosphamide, methotrexate, and fluorouracil in positive-node breast cancer patients with tamoxifen-non-responsive tumors: results from the National Surgical Adjuvant Breast and Bowel Project B-15. *JCO* 1990;8:1483-96.

Mr. GREENWOOD. Thank you, Dr. Emanuel, for your coming in and your helpful testimony. I appreciate that.

The Chair recognizes himself for 5 minutes to ask questions. Let me turn to Dr. Norton first.

It is evident from this hearing and from all of the work we've done leading up to this hearing, which has been extensive, that there is virtual unanimity among most Members of Congress with the GAO, the IG, the pharmaceutical industry, and your association that we need to get rid of AWP, that it's irrational, that it causes overpayments, cruel overpayments to beneficiaries. That is certainly inconsistent with what the intention of Medicare is. There is also, I would say, virtual unanimous consent to the notion that we need to then simultaneously, so that there is no disruption in service or no inequity imposed by our changes, come back with a way to make sure that your profession and all of the other professions that are here and that are not here who would be affected by a change in AWP are adequately and appropriately reimbursed.

Now, the GAO study says that in order to do that, we need to put about \$51 million into increasing practice expenses. Mr. Scully from CMS testified that he thought the number was somewhere between \$45 and \$55 million and that those figures were arrived at totally independently, which gives us a fair amount of confidence in the order of magnitude of those changes.

Does your association—you have submitted a white paper, et cetera. I have a sneaking suspicion that your association thinks that the number might be a bit higher than that. Are you putting a number on the table here?

Mr. NORTON. We don't think we have the data—we don't think that anybody has the data to come up with an accurate number,

frankly. It gets down to fundamental logical issues about what it actually costs to give chemotherapy. The GAO report we haven't seen yet, the latest one. We thought that this issue is being studied carefully. We're—and I think we're going to have to scrutinize the report to see whether the report which just came out to today really does address the issue, but the only real way we feel that you can actually figure out the cost is to measure the cost of what is really required, how much nursing time is required, the cost of the syringe, the cost of the IV tubing, cost of the needles, the cost of the tape. All these things are costs, the inventory of drugs, spillage, wastage, all these issues that are involved, and we really don't have that data.

We will be very happy to do a survey to collect that data. We'll be very happy to work with the government, anybody who Congress designates to work to actually get that data, but just looking at this as a scientist, I don't think that the methods really are giving us the numbers we really need to figure out what the true costs are.

Mr. GREENWOOD. Thank you. While I am posing this next question, if Mr. Martyn and Mr. Connaughton would separate yourselves and, Mr. Scanlon, if you would bring a chair up and I am going to ask you to comment after I ask Dr. Norton another question.

In your testimony, Dr. Norton, you said that—and I am quoting—"Oncologists and their professional staffs typically furnish a variety of services to cancer patients for which there is no explicit reimbursement. These services include extensive support that seriously ill cancer patients frequently require, including social work services, psychosocial services, nutrition counseling. Social work services encompass a variety of services intended to help patients carry out their therapy, such as help with insurance, arranging transportation to treatment and filling prescriptions. Psychosocial support includes services such as counseling patients on their activities of daily living, support groups that meet in the physician's office and grief counseling. In addition, physicians treating cancer patients perform an extraordinarily high amount of work outside the patient's presence, including family counseling, telephone calls, arranging for entry into clinical trials, and so forth."

And I don't doubt any of that and I have visited oncologists in my district and I have heard from them and from their staff similar concerns.

Let me actually turn to Mr. Scanlon, and if you will pull the microphone up. I would assume that there are other medical specialties that either provide or would like to provide and be reimbursed for these services. Does Medicare reimburse anyone for these kinds of services in addition to their regular fees?

Mr. SCANLON. Not explicitly. The issue here with oncologists and other specialties, the way that the system has been constructed, is that the costs of these kinds of services to the extent that they are incurred by a practice are included in calculating fees but they are distributed across the procedures and the services that are being recognized by Medicare. This is something that is related to the American Medical Association, which is establishing the CPT, the current procedural local terminology system, which identifies

what are discrete services that physicians are going to provide, and then there is some amendment or modification of those by Medicare. That process is what we need to look at, and as I mentioned, we are doing work on additional data. This is one of the areas where we need additional data. Should there be discrete activities that are now recognized as services and sort of why isn't it that they haven't been identified as discrete services under CPT?

Mr. GREENWOOD. Let me just ask you this. When you came forward with your \$51 million estimate to compensate to raise the practice expenses, were you assuming that any of these kinds of services would be included in that?

Mr. SCANLON. We were not assuming they would be included explicitly, but we were assuming that the costs of those services were reflected in the data that we had and that those costs were distributed—\$51 million represented distributing those costs more appropriately across different services and across different specialties. So we feel like the data and the method reflect these services, but better data may lead to a different change in fees.

Mr. GREENWOOD. Dr. Norton, your comments.

Mr. NORTON. We don't think they have the data. If they are relying—like the AMA data, there are a small number of oncology practices that were scrutinized and there was a tremendous amount of estimation involved. One thing that makes oncology different from other specialties is other specialties it's some patients that require these services. In medical oncology it's essentially everybody. As the therapies go on, as patients get sicker, as the medicines change, it sometimes gets more complex rather than less. The time the nurse spends with the patient talking about the drugs, talking about the side effects, monitoring for side effects during the infusion and between infusions, this is just essential and it's not covered at all. It's just—and it's not really reflected in the numbers. It's not really reflected in the data because it hasn't been scrutinized carefully.

Mr. GREENWOOD. Let me just bring forth, when we are talking about data here, one piece of data. A recent survey in Modern Health Care estimated that the average oncologist's salary could be as high as \$334,000 per year. Is that a figure that you think is within the ballpark, sir?

Mr. NORTON. That sounds high to me, and I've seen surveys of various medical specialties. I don't actually recall the absolute numbers but they varied a lot, again depending upon the sample that was used, the geography, and many other samples. But I do remember that medical oncologists were not outliers in terms of their income by any stretch of the imagination in terms of other medical specialists.

You know, if medical oncology were a very attractive specialty for financial reasons we would have an abundance of candidates. You know, we're having trouble filling our training programs. Everybody who trains medical oncologists is having trouble finding quality candidates for their training programs. It's not a highly subscribed specialty because it is so difficult. It is such a difficult life-style and it's not an especially lucrative life-style either.

Mr. GREENWOOD. Thank you, sir. The gentleman from Ohio, Mr. Brown, for 5 minutes.

Mr. BROWN. Dr. Norton, I have an article from the Journal of Cancer Economics, March, 1997, and I was intrigued by a speech made by a chief medical officer at United Health Care Corporation in Minneapolis to the National Cancer Centers Network, which as I understand the audience is made up of many oncologists and other people. I want to read a little bit from what he said and ask what's happened in the last 4 years. This is March 1997.

He says, "You're going to have to make chemotherapy a cost neutral equation. I would tell you that the industry is probably going to do this for you. Without eliminating the markup on drugs, I really do fear that you are going to lose credibility within organizations outside. Employers are already bringing this up to me. What are you doing about oncologists who are making too much money on drugs? My case managers are coming to see me and saying that about half my patients are dying within 2 weeks of their last chemotherapy course. So where was the oncologist saying it is time for quality of care? Let me give you good supportive care and pain relief. Let me get you into a hospice."

He then goes on to say, "The markups for chemotherapy medicines are going to be so high that the public is beginning to react. You are losing credibility from that," he tells the oncologist. "What you will see happening in my company and I suspect others is that you will no longer be getting reimbursed at average wholesale price."

What you will see happening in my company, and I suspect others, is that you will no longer be getting reimbursed at average wholesale price; you will be getting reimbursed at catalog prices. The reason for doing that is to make this decision truly a decision made, because it's the right thing to do, not because you have a financial incentive.

It sounds to me, from taking these excerpts, that managed care was not going to take it anymore; in a sense, that they were not going to pay you the—they were not going to follow the price structure that Medicare seems to.

What has happened in these 4 years?

Mr. NORTON. No, that's not an individual I know or an organization that I attend. So I don't know exactly what transpired there, what was, you know, sort of implied by all this.

Mr. BROWN. What has happened with managed care payments?

Mr. NORTON. The managed care payments generally are much lower than the actual costs of administration of the therapy. You know, sort of across the board, it really is a big issue.

Mr. BROWN. Lower than Medicare?

Mr. NORTON. I do not know the specifics, sir. I do not know the specifics.

I do know, for example, in my own center that if I didn't have philanthropy pouring into the center, I couldn't provide anyone near the services I provide. I applaud my colleagues in practice, especially small practices, for doing as much as they can with the amount of money that they have flowing in.

Mr. BROWN. So you can't tell me if Medicare—if managed care companies are paying more or less than Medicare?

Mr. NORTON. I personally cannot. I can't provide that information for you in great detail.

Mr. BROWN. Considering the markup, considering if a drug costs \$200 and Medicare is reimbursing 1,000 and the oncologist is pocketing some amount of the 800, I would think you'd give us some ball park about what might be happening with managed care companies.

Mr. NORTON. I would challenge the notion of the doctor pocketing the money. The doctor is using that money to take care of the patient. That is what is happening. It is a broken axle and it's a broken wheel. We have to understand the system is working, quality is being provided and the money coming in that's in excess of one side is balancing the other. We've all said the same thing.

Mr. BROWN. I wish you were a little better informed about the managed care side of it, because when I—I go back to Chairman Tauzin's comments earlier about the fact that the copay for many seniors is actually more than the cost of the drug that the doctor is paying. In some cases, that 20 percent is 20 percent of a much larger, huge number in some cases than 20 percent of the real cost of the drug; and I would think maybe if we were able—if anybody on this panel could give us the information about how much a drug—how much the managed care companies were paying, maybe we could help Mr. Scully come up with “20 percent of what” figures, because we don't know. We only know 20 percent of the AWP, but it would be nice to know 20 percent of the lesser figure, and perhaps the managed care companies have alighted on that figure, if you will. But apparently nobody on this panel, with as much expertise as you have, can tell me what managed care has done in the last 3 or 4 years.

Mr. NORTON. I'm not an expert in health economics, frankly. I can get the information for you, and I'd be delighted to work with you on it, but, no, I don't know that.

But I do know—

Mr. BROWN. Would you submit that for the record, please, Dr. Norton?

Mr. NORTON. Any information you need, you ask us, we'll provide.

Mr. BROWN. Thank you.

I'd like to know what managed care companies, versus what—for these 24 drugs; is that it—these 24 drugs, what managed care companies are paying, on average.

Mr. NORTON. As I said, we'll be very happy to cooperate with Congress in every way to give you the information you need.

Mr. BROWN. Good. Thank you.

Mr. EMANUEL. I just wanted to say one thing about the patients and managed care companies.

Almost exclusively, in managed care companies they do not pay a percentage of the drug, right, almost exclusively in managed care companies. If Medicare is going to look like managed care companies, they are going to have a fee schedule that is like \$5 and \$10, independent of the price of the drug. Okay? That is the way managed care companies are run now.

Now, they may be shifting because of rising prices—

Mr. BROWN. If I can interrupt, Dr. Emanuel. I don't think that—because Medicare doesn't have much of a track record of paying for drugs. Only these drugs that—and it's such a peculiar way you do

it. I don't know how you can say that Medicare will set a price and it's irrespective of the price that the drug actually costs.

Mr. EMANUEL. That is not what I said. Sorry. Maybe I was unclear.

Mr. BROWN. Tell me again. I'm sorry. I misunderstood you.

Mr. EMANUEL. In managed care, patients are—they have copays of \$5 and \$10. They are unrelated to the price of the drug.

Mr. BROWN. The copay?

Mr. EMANUEL. And Medicare is different in that it makes the copay related to the price of the drug.

If you want to make Medicare like managed care, then you fix the copay independent of the price of the drug.

Mr. BROWN. I didn't say I wanted to make Medicare like managed care in that way.

If, in fact, managed care has done what this article might suggest it will have done in the next couple of years, starting back 4-plus years ago, then we might be able to use that as a real price for these drugs. If that, in fact, is what these drugs cost from the manufacturer that managed care is paying for, then we might be able to talk more about Chairman Tauzin's 20 percent of that figure rather than 20 percent of the AWP figure.

Mr. EMANUEL. I'm not an expert on managed care pricing either, but let me just say one other thing.

One of the problems is that if you go to managed care and talk to them—and one of the other things I do in my head is talk to them about these things—they don't have a price for the drug. Just like manufacturers play around with prices to doctors and to pharmacies, they play around with drugs to managed care, so if you buy three of our drugs, we'll give you this kind of discount.

If you're only putting one on the formulary—so there is no such thing as “the price of a drug.”

Mr. BROWN. We know that, and particularly when—in light of the fact that Americans, out of pocket, pay about twice as much as what managed care companies on the average pay for the cost of prescription drugs.

So, so be it. Thank you.

Mr. GREENWOOD. The time of the gentleman has expired.

The gentleman—the chairman, Mr. Tauzin.

Chairman TAUZIN. Thank you, Mr. Chairman.

Dr. Norton, let me see if I can help understand this a bit better, and maybe you can give us some history—a bit. In terms of the way the different physician groups negotiate with CMS, formerly HCFA, for their reimbursement for practice expenses, would oncology groups actually go in and make a case for the—all of the expenses you indicated were not now covered?

Mr. NORTON. Absolutely for—

Chairman TAUZIN. Have you made that case over the years?

Mr. NORTON. If we are asked to. We have offered it. We have offered to do that, and they have said that we'll call you when we need you, but we are still waiting for the phone call.

Chairman TAUZIN. You've never had the opportunity to make a case on what your true practice expenses are?

Mr. NORTON. That is exactly right.

Chairman TAUZIN. So are you telling me that HCFA, in the past, was just not interested in hearing from you on those numbers?

Mr. NORTON. Again, what CMS or HCFA previously has done is—you know, they will have to tell you that.

I do tell you, we are very anxious to help in trying to determine these costs. We have offered it, and we've been told that we will be called when they need us.

Chairman TAUZIN. Staff is advising me that every physician group has the right on a yearly basis to submit data to refine the practice reimbursement costs. Have oncologist groups taken advantage of that opportunity under the law?

Mr. NORTON. The—my understanding is that it's done sort of collectively, but that oncologists are clearly, you know, part of a very large number of physicians that—you know, that do this. But my organization, ASCO, the American Society of Clinical Oncology, has offered on many occasions to help in determining these costs, and we're still very willing to do that.

Chairman TAUZIN. Mr. Scanlon, you're here. Could you help us with that process?

I mean, my understanding is that every group can come in every year and do that. If Dr. Norton has said they really haven't had that opportunity, I'd like to know why not and what's wrong with the process.

Mr. SCANLON. Groups do have the opportunity to come in individually. There has been additional information that's been incorporated in the practice expense that comes from the American Medical Association's survey of all specialties, but individual specialties—and thoracic surgery is one that has submitted data of its own—it involves doing a survey of its practices.

Chairman TAUZIN. So they weren't invited to do it? They did it on their own?

Mr. SCANLON. Congress gave them the right to do this in the Balanced Budget Reform Act.

Chairman TAUZIN. So the question, Dr. Norton, is why haven't oncologists on their own submitted data to have the—

Mr. NORTON. We have offered and we have been told that we will be contacted when it's appropriate for us to give the information; and we're still willing.

Chairman TAUZIN. What I'm hearing is that you don't have to offer to do it. You have a right to do it. You don't have to have an invite from them. You don't have to make an offer that is accepted. The law says that every year every specialty of practice has a right to submit new data, revised data, to ask the agency to revise the reimbursement under the pool. And my question is, why haven't you done that?

Mr. NORTON. We have had contact with numerous agencies, and we've offered our assistance in determining these prices. There's issues in costs, in fact.

Chairman TAUZIN. Well, you tell me what you did, but you're not telling me why you didn't do what you could do. So let me say it again as clearly as I can.

If you have the right to submit it without an invitation, if the law gives you the right every year to go to CMS now and say, these

are our numbers on what it takes to properly reimburse us for practice expenses, why haven't you done that?

Mr. NORTON. Well, part of it is that it's an expensive proposition to do it properly, frankly. It's—we are a voluntary organization, and it's a very expensive proposition to do that.

Chairman TAUZIN. But I don't understand that. If you're being so underreimbursed, why would—if other companies have done that, why wouldn't you do that?

Mr. NORTON. You know, we didn't create AWP; we inherited AWP. You created AWP, and the fact is, it's been working. It's a broken axle, broken wheel, but it's been working.

Chairman TAUZIN. I thought that was the answer, because that is our suspicion. The reason why we've never gotten a real definitive, you know, resolution of what the true practice costs are in some of these fields is that you felt comfortable with the AWP reimbursement as taking care of whatever deficiencies exist. Right?

Mr. NORTON. We haven't felt comfortable with AWP. We've been opposed to the whole concept ethically, morally.

Chairman TAUZIN. I'm just saying in terms of the dollars.

Mr. NORTON. The economics have worked. We're able to keep the ship afloat.

Chairman TAUZIN. So that if you didn't have the advantage of the overreimbursements under AWP, you would probably be more likely to do what other specialty groups have done every year, and that is get in there and pitch a case for why you want to be reimbursed more thoroughly for your practice expense?

Mr. NORTON. We absolutely would help determine the proper reimbursement, absolutely.

Chairman TAUZIN. Now, recognizing that that hasn't happened and recognizing that if we do eliminate this practice of overreimbursing for drugs, which some specialty groups, like your own, have relied on upon rather than seeking changes in that pool, if we did that, you would—is there any doubt you would head straight to that pool and seek a reassessment of your practice expenses?

Mr. NORTON. Oh, we would like to work to make a fair cost. Absolutely. Sure.

Chairman TAUZIN. And would it be helpful if we had your cooperation and the cooperation of other groups, specialty groups, affected, in eliminating this practice of the AWP—because it has other pernicious effects, not just this financing thing—if we got rid of it, would it be helpful if we asked you to work with GAO and the IG and Scully and our own committee to determine what is, in fact, a fair estimate of what practice—

Mr. NORTON. It would not only be helpful; it would be wonderful. We would relish that opportunity.

Chairman TAUZIN. If we told you in advance that we were prepared, and this committee was able, to support additions to the fund so that, in fact, there would be less pressure on you having to go get your dollars from some other practice group, but there would be room to make up a reasonable—in a reasonable way, commensurate with what other practice groups are getting—I'm not saying that we should favor one practice group over another in that process, but to give more room for you to adequately get a reevaluation of your practice—

Mr. NORTON. See, again——

Chairman TAUZIN. Would such a proposal meet with your support?

Mr. NORTON. Yes. It sounds great. Frankly, you know, the point is that we're not talking about consultation costs or visit costs. We're talking about actually—the cost of actually treating patients, the cost to treat patients. Any solution that enables us to be able to continue to treat our patients is a solution we'd be happy——

Chairman TAUZIN. That is the solution we want. When we started this discussion, the chairman will tell you we had briefings, and I, among a number of members, made it very clear that if we're going to do this, if we're going to take this on, this massive project to change this, when 10 years have gone by and nobody could do it, that the one outcome we could not have is that somehow you were not going to be out there taking care of cancer patients as a result. And then that's your leverage in this thing. We understand that.

But our leverage is that—I want you to understand this. Our leverage is that I don't think patients in America, upon learning that they're paying a 20 percent copay that is equal to 500 percent of the cost of a drug that the doctor buys—I don't think patients in America are going to let anybody put up with this system, now that that's out in the open; and that patients are gradually going to understand how bad that is.

I mean, when my 82-year-old mom hears that she has to pay a 20 percent copay that's equal to five times what the doctor is charged for the drug, I can tell you, I'm going to get a few phone calls from that lady, and I suspect every Member of Congress would. And if there were a legislative stand-alone proposal to change that, it probably would zip through this Congress.

So I guess my message is that we understand, I think, the problem of how we've gotten in this mess. I also want to say this again. I think you're the angels sent from God for the work you do, and I know why you're having a hard time recruiting in some cases.

It's so awful to watch people go through what people go through in cancer, and you guys do it all the time, and I admire you so much for that. I want you to understand that.

We understand the problem you're in, but we need your help to fix it. And if we're going to come up with a formula that works, we're going to need all the specialty groups working with us to come up with a solution that answers it. If we don't, we're going to end up having to sell parts of it at a time, like this 20 percent copay thing, and that's not going to be good. That's just going to take a chunk out of income.

But, in fairness, I can't see asking my mom or anybody else to pay 500 percent for some—for the cost of some drug, when the law says they ought to pay 20 percent of it. There's something wrong there.

Bottom line, I guess what I'm saying is, I think we're seeing our way to some solutions, but we're going to need the support, help and encouragement of the provider groups, such as yours, in finding it in a way that you continue and can continue to serve America's cancer patients; and at the same time that we can put an end

to this system, not simply because it may be wrong financially, but because it has some potential aspects to it that are so disturbing.

To think that the bonus paid for chemotherapy might encourage anybody to use it when it's not appropriate is just an awful thought, and I hope it does—I hope it is not happening in America. But the thought that it could is just so disturbing, that I think we have to—we have to deal with this pretty soon.

And so, again, thank you for your contributions today, all of you, and I hope we—I want to do one more thing, if I can, Mr. Chairman. I want to turn to Dr. Emanuel.

What is a nonresponsive chemo situation? You named a bunch of cancers. Tell us what that means. That means that chemo doesn't help at all?

Mr. EMANUEL. Right. The chemotherapies we have available do not shrink the cancers.

Chairman TAUZIN. Do they help with the patients in any other way?

Mr. EMANUEL. Usually they are not recommended when they don't shrink the cancer.

Chairman TAUZIN. Well, that's what I'm having a hard time understanding. Why in the Massachusetts study did you—and maybe, Dr. Norton, you can help me.

Mr. NORTON. I can help you.

Chairman TAUZIN. Why did you find that doctors were doing chemotherapy on patients when chemotherapy was known not to work?

Mr. NORTON. Generally speaking, we define “responsive” as about a 20 percent response rate. But somebody who is desperate will take less than a 20 percent response rate, and that's—frankly, I think it's one cycle. You say, Listen; the patient says, Listen, Doctor, please try.

Chairman TAUZIN. Very often, it's a patient saying, I don't want to—

Mr. NORTON. I spent 45 minutes with the daughter of a patient this morning before I came here. She was begging me to treat her mother with chemotherapy, and I frankly said I didn't think it was appropriate.

Chairman TAUZIN. So I just—

Mr. NORTON. One cycle is what Dr. Emanuel found in his study. You know, when a patient comes in, desperate, and says, Please try; and you can find in the medical literature 5, 10 percent response rates in all these diseases to various—you say, We will try one cycle; if the cancer doesn't shrink, we will stop. And frankly I don't think that is so unreasonable. You know, you say the last 6 months, the last 3 months of life; you don't know that until a patient has died. If they respond to therapy, it's no longer 3 months.

Chairman TAUZIN. I'm trying to help you. So the fact is that the bonus that exists in this reimbursement system may not be the reason why even in a nonresponsive cancer case chemo is selected, because the patient may want it in some cases.

Is that right, Dr. Emanuel? Do you agree with that?

Mr. EMANUEL. Yes. I think that's—we've all experienced that situation.

Chairman TAUZIN. Thank you very much, Mr. Chairman.